Award Number: W81XWH-10-1-0682

TITLE: Children’s Hospital Integrated Patient Electronic Record System Continuation (CHIPERS)

PRINCIPAL INVESTIGATOR: Heidi R Flori MD, FAAP

CONTRACTING ORGANIZATION: Children’s Hospital and Research Center Oakland
Oakland, CA 94609

REPORT DATE: December 2015

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
December 2015	Final	9/10/2010 – 9/9/15

4. TITLE AND SUBTITLE
Children's Hospital Integrated Patient Electronic Record System Continuation (CHIPERS)

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-10-1-0682

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Heidi R. Flori MD, FAAP

E-Mail: heidiflo@med.umich.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Children's Hospital and Research Center
Oakland Oakland, CA 94609

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
This is a prospective comparison of the management and outcomes of patients at Children's Hospital Oakland before and after the implementation of an Electronic Health Record with Clinical Decision Support (CDS) system. We are enrolling patients in the Pediatric ICU with severe sepsis/shock **(Specific Aims 1 and 3)** where time sensitive decision support spans *minutes to hours*. We are also testing CDS in the Newborn ICU with prolonged and complex nutritional needs **(Specific Aim 2)** as these patients' time sensitive decision support spans *days to weeks*. Our goal is determine whether CPOE with CDS is an appropriate tool for managing complex, critically ill patients across differing "time sensitivities" as well as determine how environmental and systems factors influence the decisions to follow established clinical guidelines. Determining the factors influencing use of time-sensitive clinical guidelines is highly likely to be generalizable to other critical management scenarios, such as stroke, traumatic brain injury and pulmonary embolus and in both adult and pediatric patients. CDS can be a powerful tool for improving the care provided by front-line clinicians to critically ill patients with complex medical needs in other diverse environments.

15. SUBJECT TERMS
clinical decision support, electronic health record, pediatric critical care, neonatal intensive care, severe sepsis, septic shock

16. SECURITY CLASSIFICATION OF: a. REPORT	b. ABSTRACT	c. THIS PAGE	17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
U	U	U	UU	80	USAMRMC

19b. TELEPHONE NUMBER *(include area code)*

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Introduction

Electronic medical record (EMR) systems are being deployed extensively throughout the United States. In addition to storing clinical data, EMR systems integrate computerized order entry (CPOE). The integration of CPOE into the EMR also provides the opportunity to include clinical decision support (CDS) systems, where diverse clinical data are used to provide algorithm-based feedback to caregivers. CPOE with integrated CDS has been shown to improve some aspects of medical care such as accuracy of pharmacy orders. However, whether CDS can improve care in more complex, *time-sensitive* areas such as the management of patients with severe sepsis/shock, or patients with complex nutritional needs, is unknown. Some studies have shown that the introduction of EMR/CPOE/CDS actually worsens patient outcomes, particularly in the intensive care unit.

This is a prospective comparison of the management and outcomes of patients at Children's Hospital Oakland before and after the implementation of an EMR/CPOE/CDS system. We are enrolling patients in the Pediatric ICU with severe sepsis/shock **(Specific Aims 1 and 3)** where time sensitive decision support spans *minutes to hours*. We are also testing CDS in the Newborn ICU with prolonged and complex nutritional needs **(Specific Aim 2)** as these patients' time sensitive decision support spans *days to weeks*. Our overarching goal is determine whether CPOE with CDS is an appropriate tool for managing complex, critically ill patients across differing "time sensitivities" as well as determine how environmental and systems factors influence the decisions to follow established clinical guidelines.

Determining the factors influencing use of time-sensitive clinical guidelines is highly likely to be generalizable to other critical care management scenarios, such as stroke, traumatic brain injury and pulmonary embolus – both in the acute and sub acute phases of illness. Similarly, if we can show that electronic CDS improves outcomes compared to well-designed clinical practice guidelines, this suggests that CDS can be a powerful tool for improving the care provided by front-line clinicians to critically ill patients with complex medical needs in other diverse environments.

Body

Specific Aim 1: *Test the utility of an EMR/CPOE/CDS system in providing closed loop feedback and decision support in the management of children with severe sepsis and/or septic shock at the time of presentation to the hospital, and as the patient moves across different departments within the hospital.*

Hypothesis: We will test the hypothesis that implementation of an EMR/CPOE/CDS system will improve compliance in treating children with severe sepsis and/or shock with the American College of Critical Care Medicine (ACCM) and Children's Hospital & Research Center Oakland Clinical Guidelines for Hemodynamic Support of Neonates and Children with Severe Sepsis and Septic Shock.

Hypothesis: We will test the hypothesis that implementation of an EMR/CPOE/CDS system will decrease time to reversal of shock, decrease duration of mechanical ventilation, decrease

duration of vasoactive medication administration, decrease incidence of multiple organ system failure, and decrease hospital and PICU length of stay.

Specific Aim 2:

Test the utility of an EMR/CPOE/CDS system in providing closed loop feedback and decision support in the nutrition management of critically ill infants in the newborn intensive care unit (NICU).

Hypothesis: We will test the hypothesis that implementation of an EMR/CPOE/CDS system will improve compliance in treating critically ill infants with the CHRCO guidelines for nutritional support of these infants.

Hypothesis: We will test the hypothesis that implementation of an EMR/CPOE/CDS system will improve nutritional status of critically ill infants in the NICU, including improve growth, decrease protein debt, and decrease caloric debt by the time of hospital discharge.

Specific Aim 3*: Systematically evaluate the factors that influence whether clinicians follow clinical guidelines, and use this information to drive the design of the CPOE/CDS elements of the EMR.*

Study Design:

This project involved three phases of study as follows:

- **Phase 1 (July 2010 through Winter 2011/2) – This phase has been completed.**
  Phase 1 is the baseline period during which we have general guidelines *without formal clinical practice guidelines (CPGs) or order sets.* During this phase we collected data on compliance with the guidelines and clinical outcomes. We also evaluated clinicians' understanding of current sepsis and nutritional support guidelines to develop an understanding of the current workflow and decision-making processes.

  - Collect data on compliance with guidelines and clinical outcome of PICU patients with severe sepsis/septic shock - **completed**
  - Collect data on compliance with guidelines and clinical outcome of NICU patients requiring enteral nutrition - **completed**
  - Evaluate current practice and clinical decision-making culture and process in PICU patients with severe sepsis/septic shock - **completed**
  - Evaluate current practice and clinical decision-making culture and process in nutritional management of NICU patients - **completed**

- **Phase 2 (Winter 2011/2 until November 2, 2013) – This phase has been completed.**

  Phase 2 is a phase of *CPGs and order sets on paper.* These CPGs and order sets have been based on the information gathered in Phase 1 and following peer-referenced guidelines for best patient care. During Phase 2 we collected structured data on

clinicians' decision making as we did in Phase 1, as well as data on compliance with guidelines and clinical patient outcomes.

- Analyze data from Phase 1 and implement non-electronic (ie paper-based) decision support tools in pediatric sepsis/shock - **completed**
- Complete the PICU sepsis/shock EMR/CPOE/CDS modules – **completed**
- Analyze data from Phase 1 and complete NICU nutrition patient EMR/CPOE/CDS modules – **completed and specific aims revised based on EPIC EHR logistical constraints**
- Initiate meetings with our EPIC representatives on the timing of, plan for adapting CDS into the EPIC EMR platform (**Phase 3**) and plan for ultimate refinement of the interactive CDS tools – **completed**
- Screen and enroll all patients admitted to the CHRCO PICU meeting criteria for severe sepsis/septic shock and collect data on compliance with guidelines, clinical outcomes, and clinical-decision making as in Phase 1 – **completed**
- Continued design of PICU sepsis/shock EMR/CPOE/CDS modules – **completed**
- Continued design of NICU nutrition EMR/CPOE/CDS modules – **in progress**

- **Phase 3 (November 3, 2013 through September 2015) – In progress.**
  Phase 3 will be the post-EMR/CPOE/CDS period when the CPGs and order sets developed for Phase 2 are *embedded into the new EMR system*. As in Phases 1 and 2, we are collecting structured data on clinicians' decision-making as well as data on compliance with the guidelines and patient clinical outcomes.

  - Implement new EPIC EHR system at Children's Hospital Oakland - **completed**
  - Continue meetings with our EPIC analysts on the adaptation of CDS into the EPIC EHR platform and continual refinement of the interactive CDS tools – **in progress**
  - Screen and enroll all patients admitted to the CHRCO PICU meeting criteria for severe sepsis/septic shock and collect data on compliance with guidelines, clinical outcomes, and clinical-decision making as in Phases 1 and 2 – **in progress**
  - Continue re-design of NICU nutrition EMR/CPOE/CDS modules – **in progress**
  - Orient and re-orientation of staff to new EMR/CPOE/CDS system hospital-wide – **completed**
  - Complete data collection on compliance with guidelines, clinical outcomes, and clinical-decision making as in Phases 1 and 2 – **completed**
  - Analyze data: compare compliance and patient outcomes across Phases 1, 2 and 3 – **in progress**

All of our specific aims will be completed by comparing the management of a cohort of patients treated *after* (Phase 3) the implementation of our EMR/CPOE/CDS system to age-matched and severity-of- illness-matched controls treated *before* (Phases 1 and 2) the EMR/CPOE/CDS system implementation.

Problems Encountered:

1) **Delayed selection of and “go live” for EPIC Electronic Health Care platform at Children’s Hospital Oakland (CHO).**

This award generated in TATRC FY09 with the intent of the award to allow CHO to create, integrate and evaluate the implementation of EHR based CDS tools before and after EHR initiation at CHO. Unfortunately, the greatest challenge to this research in regards to the TATRC timeline has been the delay in EHR selection at CHO (Epic Platform) with subsequent delay in the EPIC “go live” at CHO. Although this delay in “go live” required a 5-year no cost extension, it also allowed for a greater number of subjects to be included in our studies and therefore more robust statistical power for this single center investigation. Accordingly also, this delay required a change in timeline for our phases of study, particularly for Specific Aim 1.

In November 2013, Children’s Hospital Oakland transitioned to the EPIC Electronic Health Care platform. We anticipated that for the first 6 months or more after this implementation, hospital-wide faculty and staff would be unable to fully understand and effectively implement an innovative clinical decision support system on top of the challenges of using electronic healthcare platforms for the first time. Therefore, we intentionally crafted the first months of Phase 3 as a “wash in” phase wherein severe sepsis/septic shock order sets were EPIC enabled but not interactively devised and our sepsis assessment tool was created and tested but in a background “sandbox” environment (ie not in the “live” production environment).

2) **Upgrade of initial CHO Epic platform to 2014 version.** In spring 2015, the CHO Epic team initiated a 9-month upgrade from the original Epic platform version to the 2014 Epic platform. This upgrade has drastically decreased the availability of key Epic Information Technology support staff to our research effort. Accordingly, we have utilized services of Mr. Joseph Gordon, Analyst for the Cumberland Group to assist us in continued iteration of our interactive BPAs and order set technology. The Cumberland Group has been the primary consulting group assisting the entire inpatient and outpatient CHO environment with the Epic platform initiation, maintenance and development and has been contracted with CHO for these services since 2012. That said, the intent of our research work is to continue to move our CDS into routine patient care at CHO. To effect this goal, our June 2015 spend plan clearly describes our continued contracting with Cumberland through spring 2016 and our transition plan with the CHO IT team. This plan will to allow for continued BPA development and iteration during the upgrade period, while also effecting a seamless transition of BPA and order set maintenance and reporting (currently being completed by Cumberland) to be assumed by the CHO IT team.

3) **Need for revision of inclusion criteria for Specific Aim 2 based on irreparable deficiencies in the Epic platform.**

The second impediment to this research regards implementation of CDS in the Epic platform for patients in Specific Aim 2 critically ill infants with complex nutritional needs. As described previously, like MOST EHR systems available in the US, the EPIC CPOE platform does not support complex *parenteral* nutrition ordering for infants and children. Dr. Flori and Ms. Jeanette Asselin, research coordinator and manager for Specific Aim 2, have met several times

with many members of the CHO NICU faculty and modified the inclusion and exclusion criteria to enable analysis of high risk NICU infants with complex enteral nutrition needs. This change has not delayed this aim substantially since the paper-based nutritional guidelines currently in use and being tracked as part of this grant application have included both enteral and parenteral guidelines. Specific Aim 2 has *not* been modified; only the inclusion and exclusion criteria have changed to enable the Aim to be studied completely.

4) **Change in Primary Investigator:** Dr. David Durand. current Chief Medical Officer at CHO, was the initial Primary Investigator for this project. In 2012, Dr. Heidi Flori assumed responsibility for this role for the remainder of this grant award period. Dr. Durand was also the PI for Specific Aim 2 of this project. With his transition to CMO, Dr. Flori worked together with other faculty in the CHO Neonatal Intensive Care Unit as well as Ms. Jeanette Asselin and assumed responsibility for completion of Specific Aim 2.

Key Research Accomplishments according to proposed tasks/specific aims:

Specific Aim 1: *Test the utility of an EMR/CPOE/CDS system in providing closed loop feedback and decision support in the management of children with severe sepsis and/or septic shock at the time of presentation to the hospital, and as the patient moves across different departments within the hospital.*

This Aim has spanned 3 phases. In phase 1, the research team evaluated "current practice" for pediatric patients admitted from outside hospitals (OSH), the CHO Emergency Department (ED) and acute care wards to the Pediatric Intensive Care Unit in relation to management according to the Society for Critical Care (SCCM) international Surviving Sepsis guidelines. In Phase 2, we implemented a multi-modality, house wide education program and "paper based" clinical decision support (CDS) guidelines and patient identification tools to evaluate the additive effect these strategies would have on the compliance with Surviving Sepsis management bundles and clinical outcomes of these patients. <u>These non-EMR based modalities initiated in Phase 2 and continue to be implemented and include:</u>

a) Hands-on demonstrations of EZ intraosseous placement,
b) Distribution of handout materials and
c) Lecture presentations to faculty, nurses and resident staff. The Severe Sepsis Education was added as the nurse **"High Risk Low Volume" educational focus** hospital-wide and has since been adopted as an **annual Health Stream Education** Module for all orienting and existing nursing staff. **(Appendix 1)**
d) Hospitalist staff were educated via a GOTO-based webinar/lecture for those unable to attend any of the in-person faculty meeting lectures.
e) The Clinical Practice Guideline and sepsis assessment tool **(Appendix 2a and 2b)** was been placed in all patient charts and Code Carts on the acute care wards and made available for all referring pediatricians.
f) Laminated cards with the sepsis algorithm were created for clinicians to place on their ID badge lanyards.
g) We have and will continue to present our Severe Sepsis Patient Assessment and Severe Sepsis Clinical Decision Support algorithm in lecture format at all Nursing

Skills Days and New Nurse Orientation programs, all PALS (pediatric advanced life support) courses as well as individual presentations at physician faculty meetings.

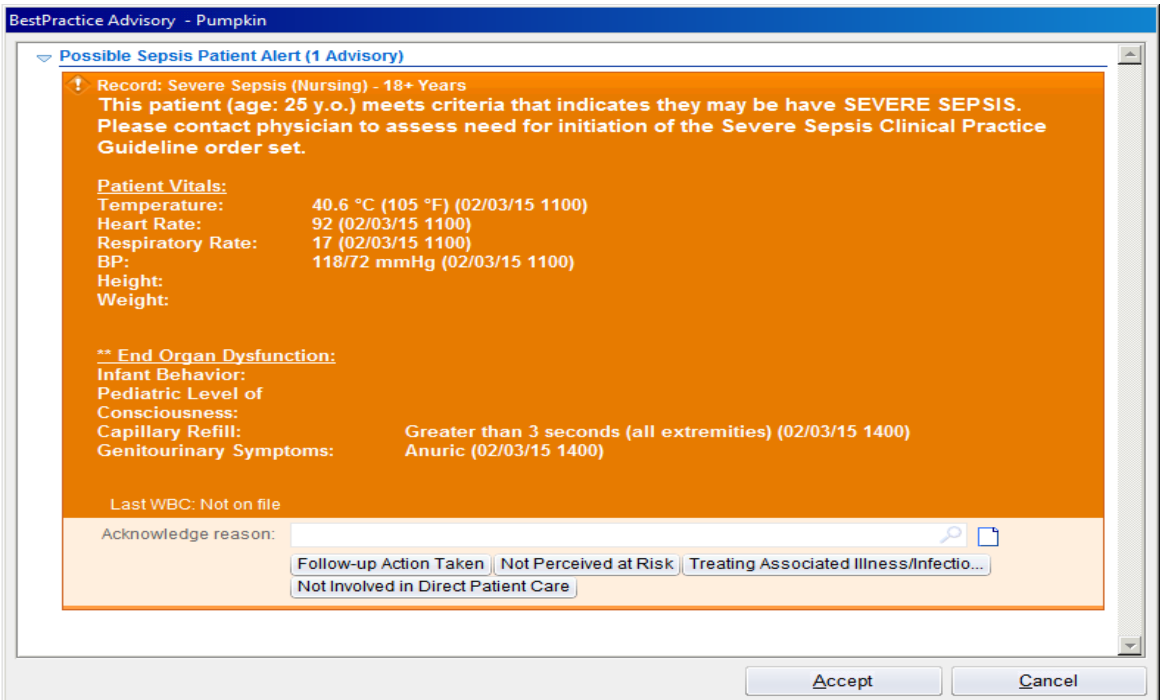
h) We continue to distribute the Severe Sepsis Patient Assessment and Severe Sepsis Clinical Decision Support algorithm electronically to all faculty with other pertinent educational materials on World Sepsis Day, each September.

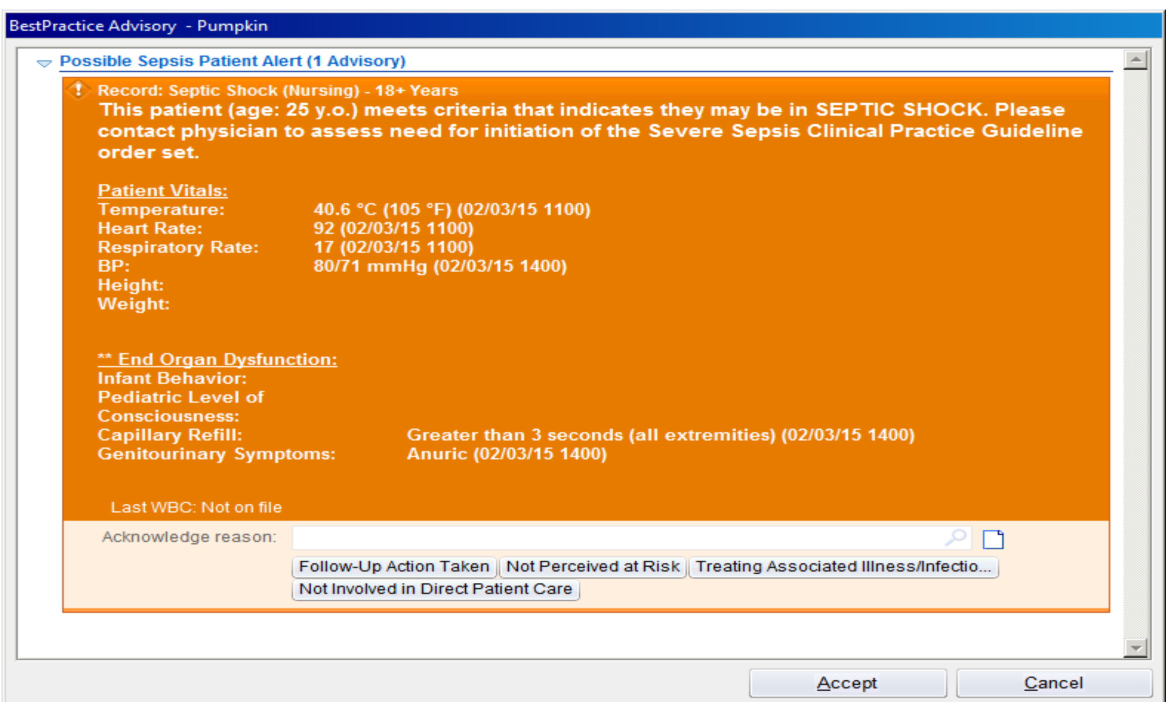
In Phase 3, these patient identification tools and management algorithms were embedded into an interactive, real time, Epic-based clinical decision support system. Our BPA logic includes:

<u>Severe Sepsis Alert Logic Summary:</u>
Age + Temperature + White Blood Cell and (lethargy or poor perfusion or decreased urine output).
Age + Temperature + Respiratory Rate and (lethargy or poor perfusion or decreased urine output).
Age + Temperature + Heart Rate and (lethargy or poor perfusion or decreased urine output).
Age + Respiratory Rate + White Blood Cell and (lethargy or poor perfusion or decreased urine output).
Age + Heart Rate + White Blood Cell and (lethargy or poor perfusion or decreased urine output).

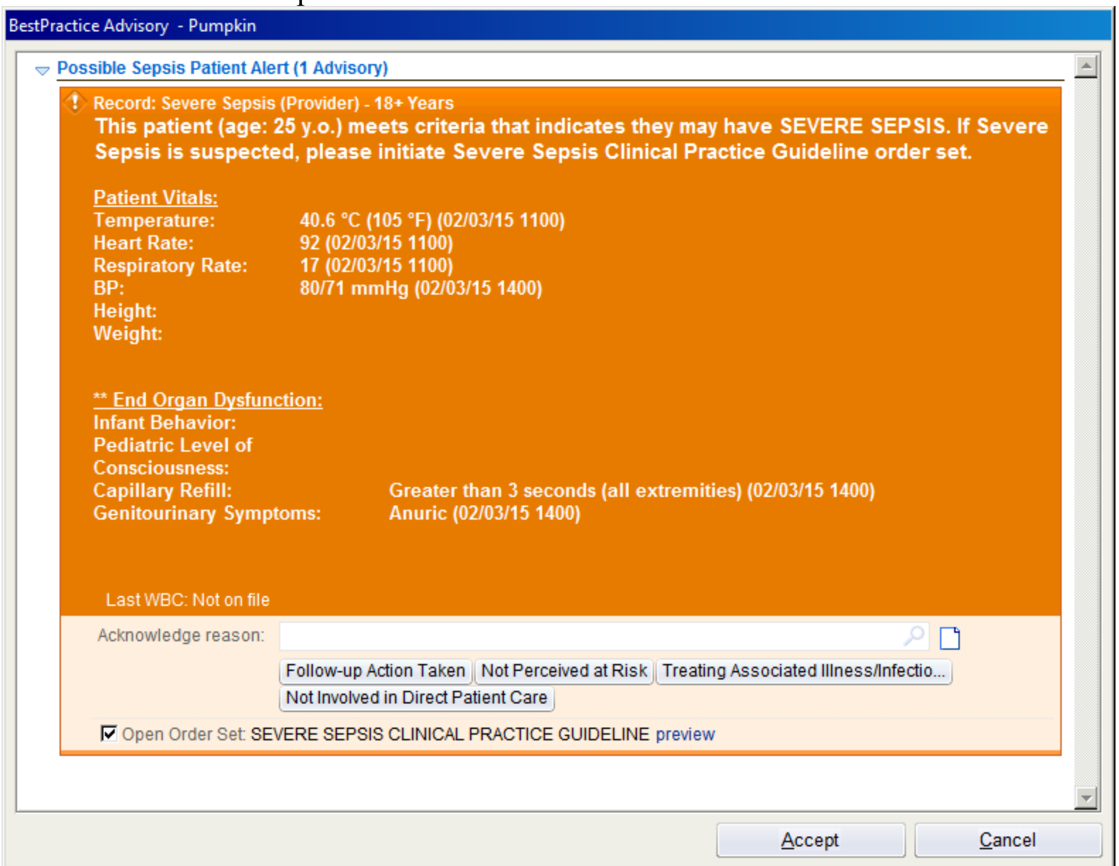
<u>Septic Shock Alert Logic Summary:</u>
Age + Temperature and White Blood Cell and Systolic Blood Pressure
Age + Temperature and Respiratory Rate and Systolic Blood Pressure
Age + Temperature and Heart Rate and Systolic Blood Pressure
Age + Respiratory Rate and White Blood Cell and Systolic Blood Pressure
Age + Heart Rate and White Blood Cell and Systolic Blood Pressure

BPA alerts exist for patients meeting Severe Sepsis and/or Septic Shock criteria. BPAs are similar for both nursing and physician staff although physician staff may access the Order Sets directly from the BPA as well. An example of the intial Severe Sepsis and Septic Shock BPA for patients > 18 yo is shown below for both nursing staff and physician provider.

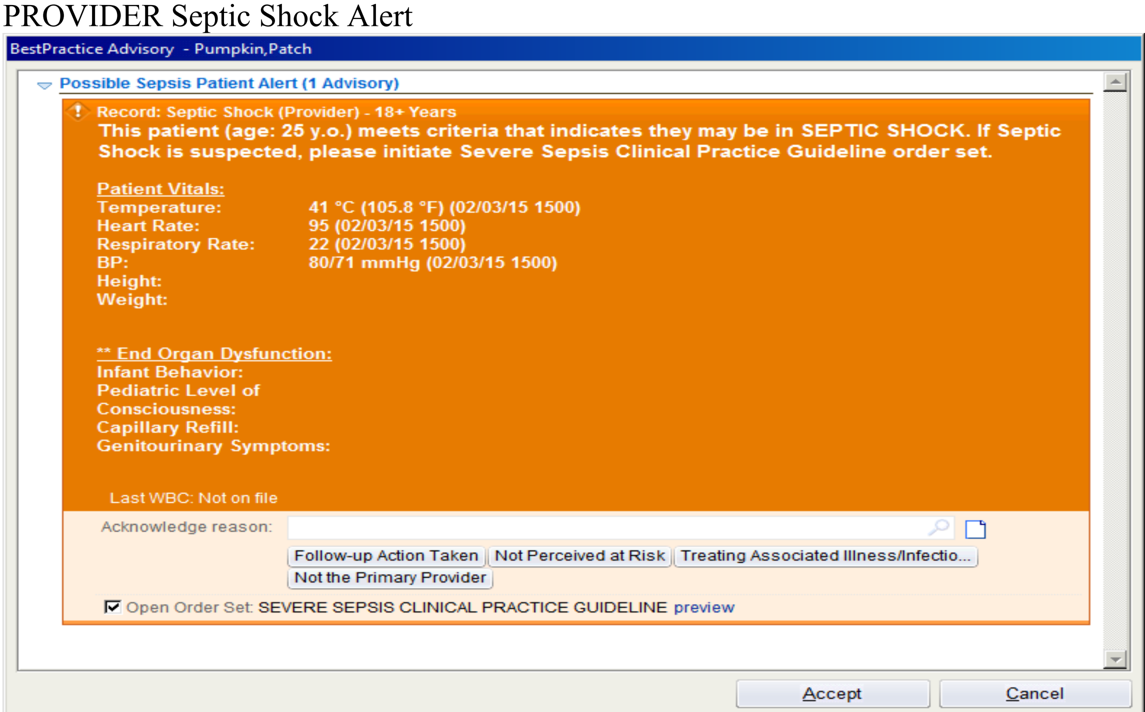




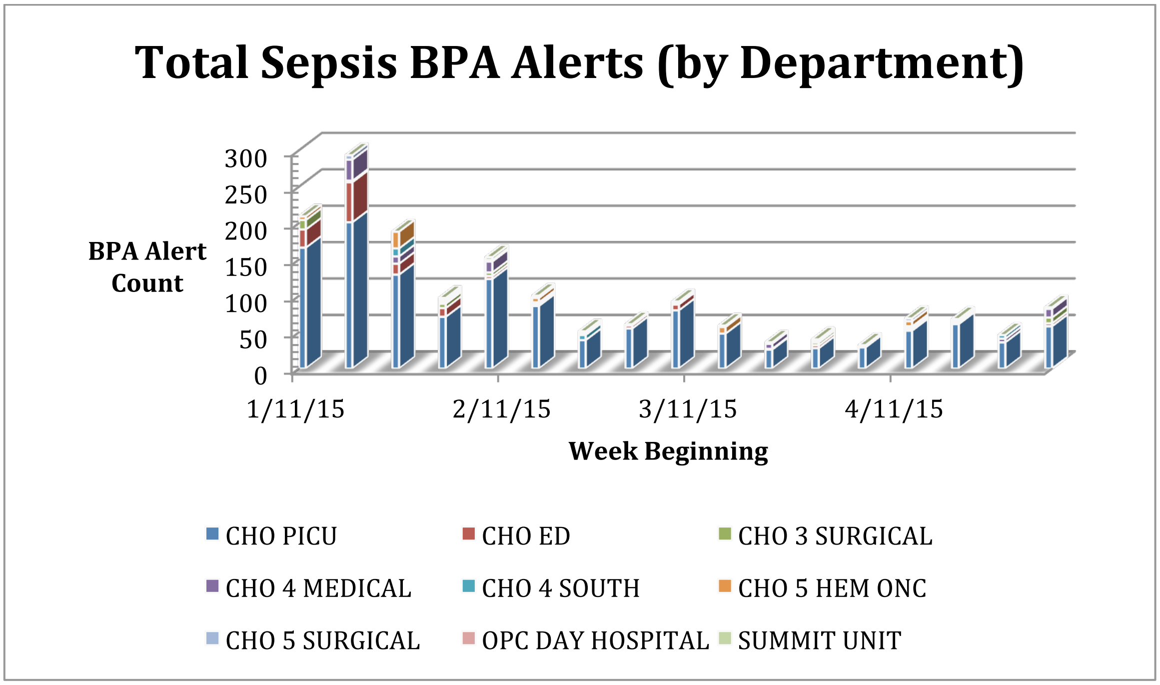
PROVIDER Severe Sepsis Alert



PROVIDER Septic Shock Alert

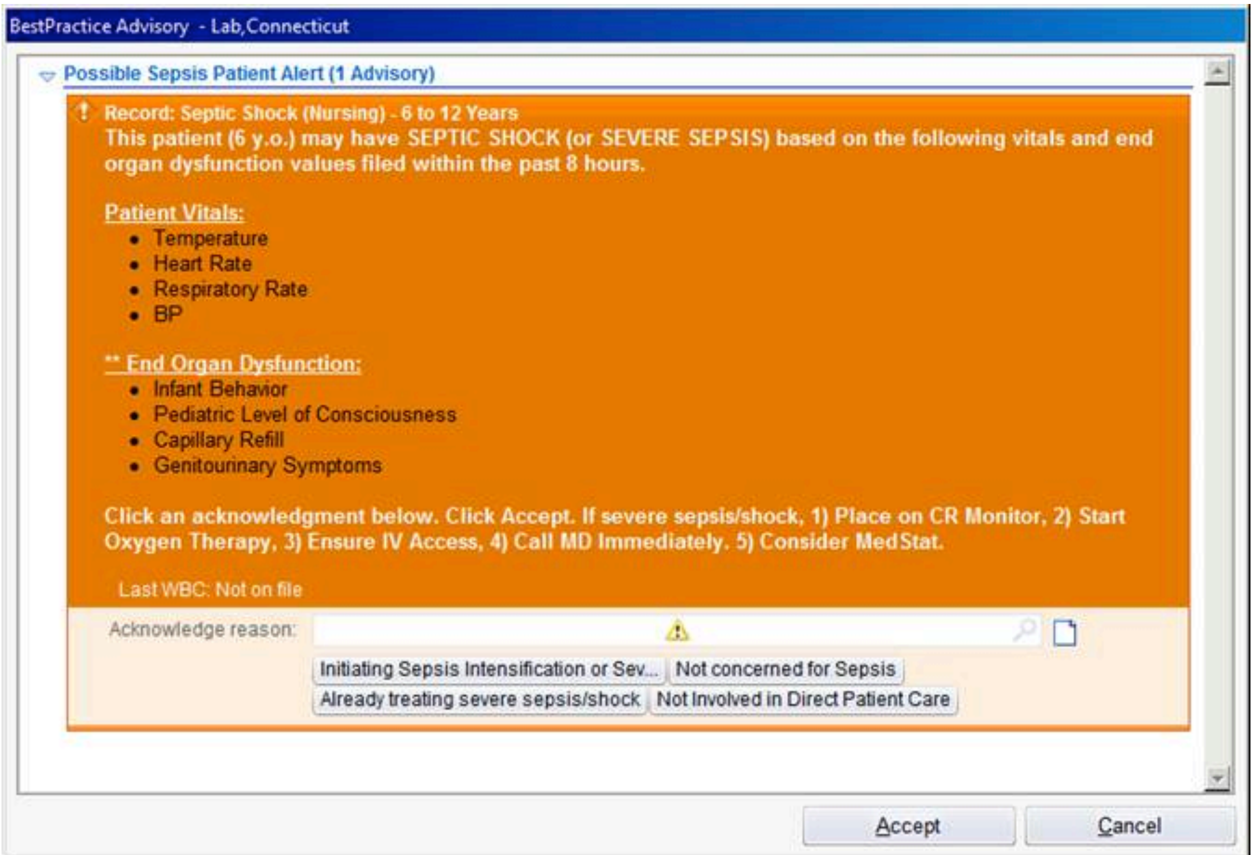


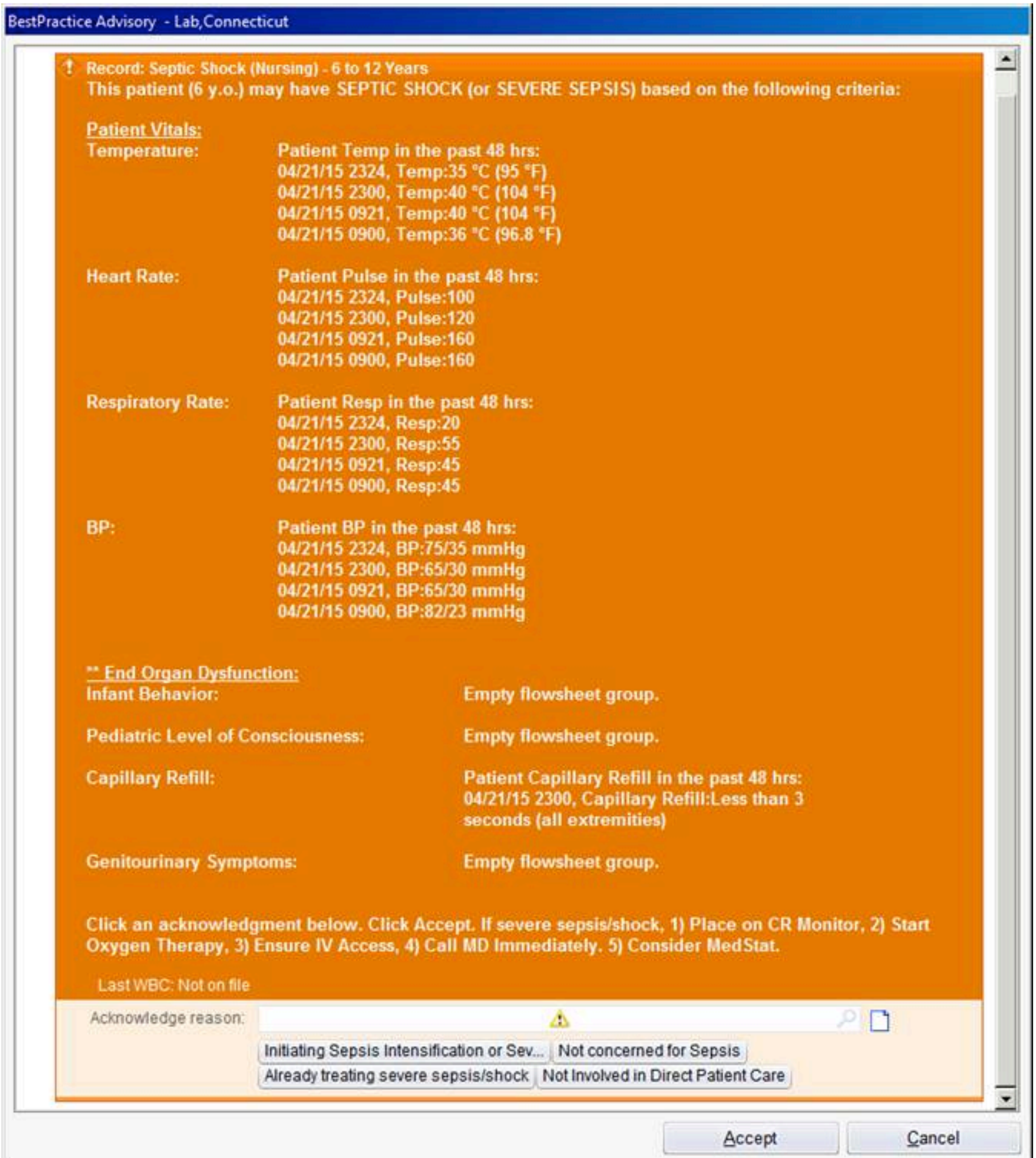
The alerts displays once per 8-hour period to each provider that accesses the patient medical record. The provider must respond to the alert for the screen to be extinguished. If appropriate, the provider can immediately access the Severe Sepsis Order Set **(Appendix 3)** from the BPA screen and/or call for Rapid Response Team activation. Weekly reports are created by the Epic and Epic Analyst team; these reports describe which patients receive the BPA house-wide, which clinicians receive these alerts and how each clinician responds to these alerts.

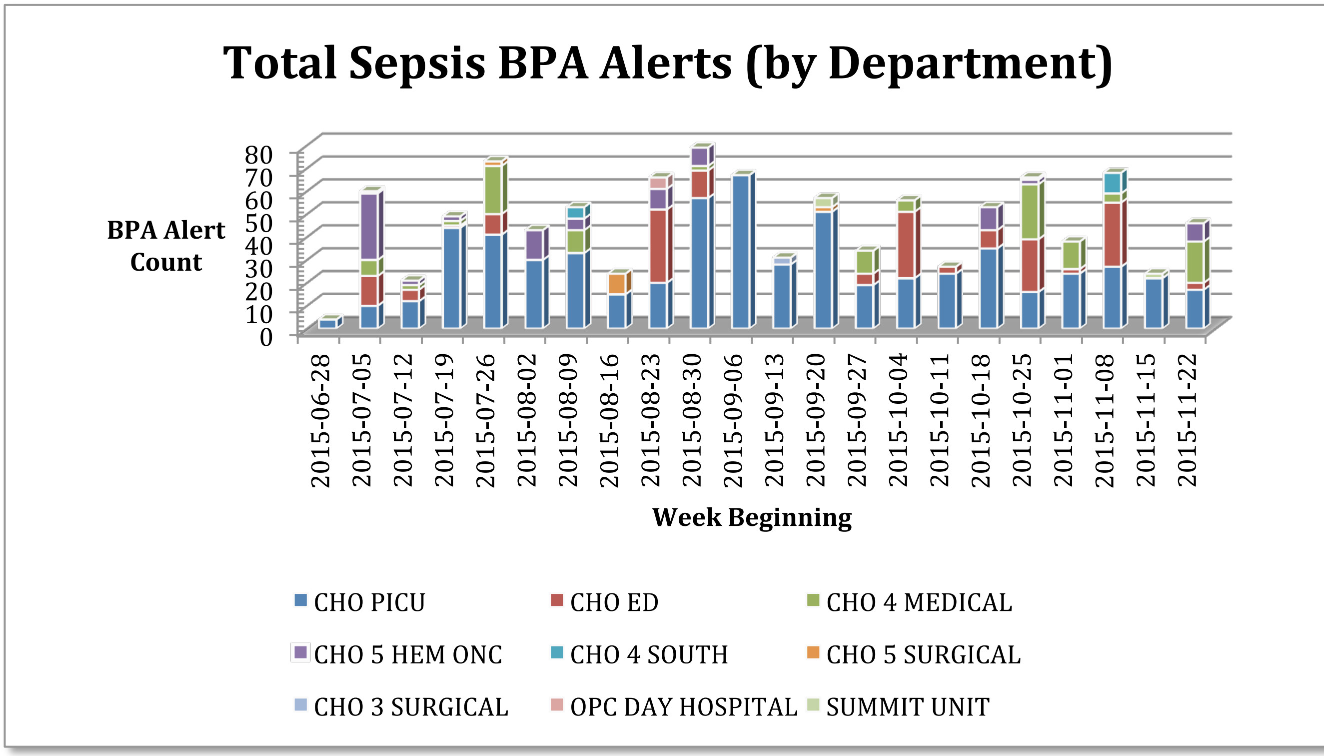


Research team members interview recipients of these alerts and interview them with a scripted set of questions (**Appendix 4**) to review areas of alert fatigue as well as areas that are well received and require further development. With this information, the research team has engaged in several PDSA (Plan/Do/Study/Act) cycles and iterated the BPA logic such that the criteria for vital signs for each BPA "looks back" for 2 hour periods in the PICU and 4 hour periods for the acute care wards. Further, end organ dysfunction criteria (urine output, lethargy, perfusion) are limited to an 8 hour look back on both the acute care wards and the PICU based on routine charting of these data elements based on nursing care. With these PDSA cycles and BPA logic adjustments, the overall number, location and response rates to the BPAs have improved substantially and appear optimally targeted for the acute care ward areas. Nonetheless, the number of patients receiving the BPA in the PICU environment and ED continue to be optimized.

The revised BPA based on RN and MD feedback follows:




BestPractice Advisory - Lab,Connecticut
Record: Septic Shock (Nursing) - 6 to 12 Years
This patient (6 y.o.) may have SEPTIC SHOCK (or SEVERE SEPSIS) based on the following criteria:
Patient Vitals:
Temperature:
Patient Temp in the past 48 hrs:
04/21/15 2324, Temp:35 °C (95 °F)
04/21/15 2300, Temp:40 °C (104 °F)
04/21/15 0921, Temp:40 °C (104 °F)
04/21/15 0900, Temp:36 °C (96.8 °F)
Heart Rate:
Patient Pulse in the past 48 hrs:
04/21/15 2324, Pulse:100
04/21/15 2300, Pulse:120
04/21/15 0921, Pulse:160
04/21/15 0900, Pulse:160
Respiratory Rate:
Patient Resp in the past 48 hrs:
04/21/15 2324, Resp:20
04/21/15 2300, Resp:55
04/21/15 0921, Resp:45
04/21/15 0900, Resp:45
BP:
Patient BP in the past 48 hrs:
04/21/15 2324, BP:75/35 mmHg
04/21/15 2300, BP:65/30 mmHg
04/21/15 0921, BP:65/30 mmHg
04/21/15 0900, BP:82/23 mmHg
** End Organ Dysfunction:
Infant Behavior:
Empty flowsheet group.
Pediatric Level of Consciousness:
Empty flowsheet group.
Capillary Refill:
Patient Capillary Refill in the past 48 hrs:
04/21/15 2300, Capillary Refill:Less than 3 seconds (all extremities)
Genitourinary Symptoms:
Empty flowsheet group.
Click an acknowledgment below. Click Accept. If severe sepsis/shock, 1) Place on CR Monitor, 2) Start Oxygen Therapy, 3) Ensure IV Access, 4) Call MD Immediately. 5) Consider MedStat.
Last WBC: Not on file
Acknowledge reason:
Initiating Sepsis Intensification or Sev...
Not concerned for Sepsis
Already treating severe sepsis/shock
Not Involved in Direct Patient Care
Accept
Cancel



Order Set Usage:

In addition to improved and earlier patient identification with severe sepsis and septic shock, our research, both in Phases 2 and 3, have focused on improved management of these patients once identified. As described above, order sets have been created and embedded with the Epic platform and are accessible from both from the BPA and individually. From 7/2015 through 11/30/2015, the order set has been accessed via the BPA 25 times within the CHO Emergency Department, 12 times from the Pediatric Intensive Care Unit (patients primarily arriving to the PICU in transport from outside hospitals), and twice on the inpatient wards. Rapid response team activation as a result of the BPA is currently being tallied.

Patient Outcomes:

A detailed analysis of bundle compliance and patient care outcomes across the multiple patient care areas is still in process and will readily be supplied to the Department of Defense on request as they are completed. Over the study period, 50 patients were enrolled in Phase 1, 67 in Phase 2, 56 in Phase 3. *The preliminary data below strongly suggest that earlier recognition of severe sepsis has occurred throughout the institution such that more patients are presenting in severe sepsis rather than in overt shock. Similarly, a significant and sustained decrease in hospital stay has occurred for these patients and is suggested in the last phase for PICU length of stay as well.*

Variable	Phase 1	Phase 2	Phase 3
Number patients	50	67	56
Male Gender (%/n)*	48% (24)	69% (46)	34% (19)
Age (mean/SD)	8.6y (6)	8.5 (6)	8.6 (6.3)

Presenting in Shock (%/n)*	**10% (5)**	**15% (10)**	**5% (3)**
PRISM (mean/SD)	9.3 (7.2)	9 (10.5)	8.2 (7.3)
Total Fluid Bolus Volume (Mean/SD)	62.5 mL/kg (37.1)	72.2 (25.7)	67.9 (16.3)
Central Venous Access (%/n)*	**24% (12)**	**41% (28)**	**48% (27)**
Time to resolution of cardiovascular failure (days)	1.09 (2.22)	2.63 (4.33)	2.27 (4.01)
Ventilator Days (Mean/SD)	3.3 (2.3)	6.6 (6.5)	5.1 (5.4)
PICU Days (Mean/SD)	**8 (10.5)**	**8.4 (10.4)**	**7.2 (8.1)**
Hospital Days* (Mean/SD)	**18.6 (13)**	**18.2 (25.9)**	**15.6 (18.6)**
Hospital Days (median)*	**13**	**10**	**10**
Mortality (%,n)	**10% (5)**	**13.4% (9)**	**7.1% (4)**

* $p < 0.05$

Time to event analyses for first antibiotics received, first point of care testing, time to transfer to Pediatric Intensive Care Unit, time to first fluid boluses and resolution of organ failure remain incomplete.

Specific Aim 2:

Test the utility of an EMR/CPOE/CDS system in providing closed loop feedback and decision support in the nutrition management of infants in the newborn intensive care unit (NICU). We will test the hypothesis that implementation of an EMR/CPOE/CDS system <u>will improve compliance in treating NICU patients</u> according to the CHRCO guidelines for nutritional support of the newborn. We will test the hypothesis that implementation of an EMR/CPOE/CDS system <u>will improve nutritional status of infants in the NICU, including improve growth, decreased protein debt, and decreased caloric debt at the time of hospital discharge</u>.

Using the revised inclusion/exclusion criteria for NICU infants, we queried the larger cohort of all infants (430) admitted within 14 days of life and staying a minimum of 28 days between Jan 2010 and Dec 2013. We felt that these criteria would define a population at risk for under and over nutrition and generate adequate numbers to allow the design and implementation of the proposed EMR programming. Data was collected and reviewed. We also chose to involve additional NICU physicians and the NICU nutritionists, to review and discuss the results of this NICU growth data, and examine impediments to consistent, ongoing optimization of nutrition.

Despite daily review of caloric intake and weight gain, some NICU infants show inadequate or excessive growth trajectories over time. Clinical group discussions identified several areas to target for EMR/CPOE/CDS intervention. Several important programmed "alerts" were added to the EMR, to assist the clinical team in evaluating the velocity of growth and identifying excessive or inadequate weight change over time. The investigators discussed triggers for alerts with the NICU clinical team. NICU physicians showed interest in assessing

those babies that grow too fast as this has been correlated with a higher risk of adult cardiovascular disease.

Since NICU infants may be hospitalized from days, to weeks, to months, the decision was made to make the NICU Nutrition EMR Programming active once babies have been hospitalized for 2 weeks. The EMR was used to look at the recorded weights starting at the 14-day point. 14 days was chosen to avoid the initial days of hospitalization when the infant's condition is being stabilized and allow a week for clinical team to begin to fine-tune nutrition. This weight was compared to the weights obtained over the previous 7 days.

EPIC programmers were be asked to develop the following "Alerts" to draw physician attention to possible unhealthy trends in infant growth:

1. Growth velocity below 10 grams/kg/day averaged over past week as an indicator of. too slow a growth velocity.
2. Growth velocity above 30 grams/kg/day averaged over past week as an indicator of excessive growth velocity.
3. Weight that started above the 25th percentile and has fallen below the 25th percentile to alert the clinical team that the infant has fallen off the growth curve.
4. Weight that started below the 75th percentile and has crossed above the 75th percentile to alert the clinical team that infant's weight gain trajectory is too high.

Implementing the NICU Nutritional Alert system into EPIC - <u>Specific Aim 2:</u>

A) Our NICU Nutritional "Alert" team worked with the EPIC programming team to design and implement nutrition "Alerts" into the NICU EMR screens. The BPA "logic" includes continuous evaluation of NICU patients meeting criteria for growth velocity outside of listed ranges. We were able to complete 2 of our 4 alerts of negative trends in growth.

<u>Growth Velocity Alert Logic Summary:</u>

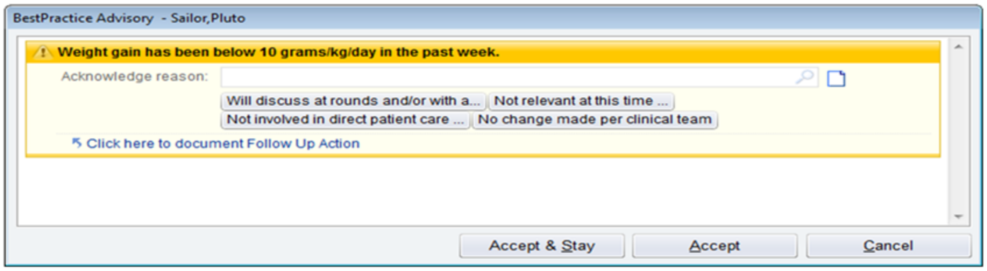
1. [Add past 7 days daily weight change /7] < 10 grams/kg/day. (Length of stay must be at least 14 days.)
2. [Add past 7 days daily weight change /7] > 30 grams/kg/day. (Length of stay must be at least 14 days.)

The NICU went live for alerts 1 and 2 in Q1 2015. The "Best Practice Advisory" appeared for individual providers upon opening a NICU patient's chart for those infants, who met one of the two triggers. Similar, but independent BPAs were used to alert the physician provider and bedside nurse (below).

Examples of Alerts:

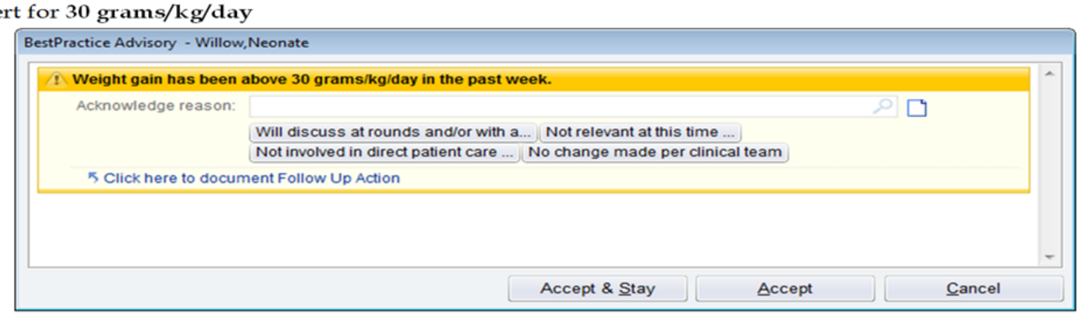
1. Growth velocity below 10 grams/kg/day averaged over past week. Indicating too slow a growth velocity.

- Alert for 10 grams/kg/day



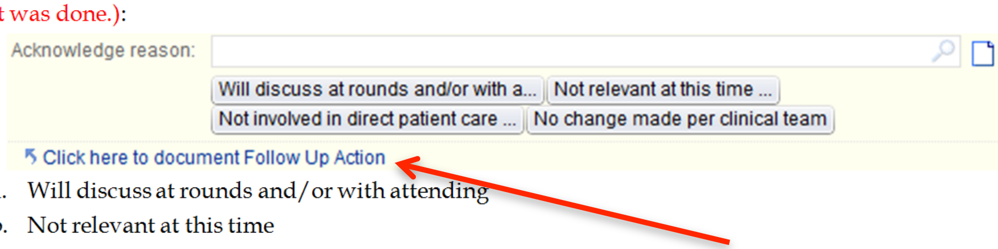
2. Growth velocity above 30 grams/kg/day averaged over past week. Indicating possibly excessive growth velocity.

- Alert for 30 grams/kg/day



Each Acknowledge Reason controlled the alert differently. Individual users could acknowledge the alert by clicking one of the buttons that would suppress the BPA for the day. Selecting and documenting a Follow Up Action would prevent the BPA from firing for one week for all users.

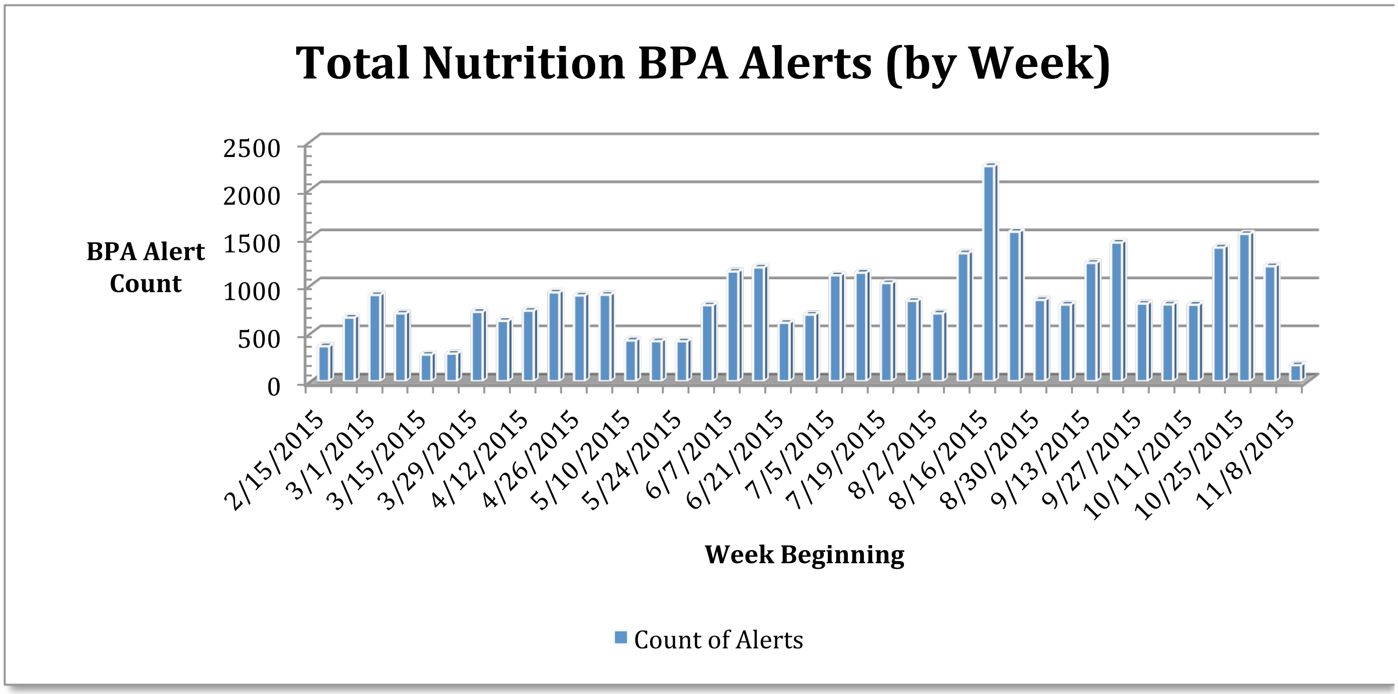
1. When the advisory appears, there are five actions to choose from (Four comments and a Follow-Up Actio of what was done.):



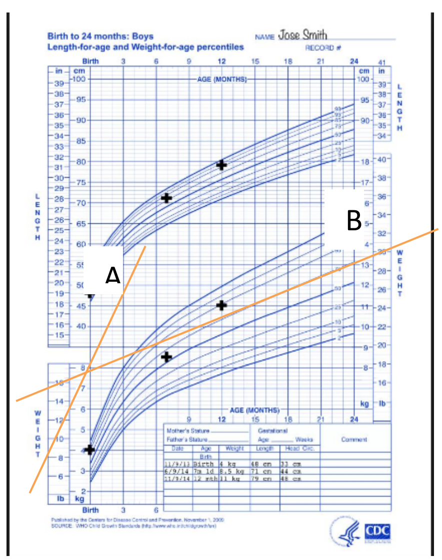
   a. Will discuss at rounds and/or with attending
   b. Not relevant at this time
   c. Not involved in patient care
   d. No change made per clinical team
   e. Follow Up Action 

The initial BPA design has required some fine-tuning. The primary concern of users was that the Follow-Up action (red arrow above) was a link rather than a button, and it was, therefore, not intuitive that this was a choice. Clinicians found the alerts to be helpful as additional reminders to review growth velocity but also complained that the alerts were firing much too often resulting in alarm fatigue.

With our initial design, we thought that our alert programming had a high enough threshold to avoid “nuisance” alerts. However, we found that, although the alert was alarming as designed, it still alarmed too frequently as an infant grew.



Ten (10) grams/kg/day is appropriate for a preterm infant in the first months of age, but was not for the term infants who may gain only at a rate of 6 grams/kg/day in the first weeks of life. As you can see in the growth curve below, there is a greater slope for growth in the early weeks of life (A) than there is at 3-6 months of age (B). Therefore, since daily growth expectations should decrease as the infant gets older, the alerts should be adjusted for older infants.



After discussion of the issue, and review of the CDC and WHO growth charts (see above), the following alert adjustments were made to better align with the infant growth curves:

a) For infants with corrected gestational age (CGA) < 37 weeks, and until they reach 37 weeks CGA, the following alert adjustments were made:

1. Alert will fire if Growth velocity below 10 grams/kg/day averaged over past week.
2. Alert will fire if Growth velocity above 25 grams/kg/day averaged over past week.

b) For infants with CGA $\geq$ 37 weeks, until they reach 48 weeks CGA, the following alert adjustments were made:
1. Alert will fire if Growth velocity below 6 grams/kg/day averaged over past week
2. Alert will fire if Growth velocity above 10 grams/kg/day averaged over past week.

Specific Aim 3*: Systematically evaluate the factors that influence whether clinicians follow clinical guidelines, and use this information to drive the design of the CPOE/CDS elements of the EMR.*

The iterative results of our focus groups have been presented at two national (Society for Pediatric Research in 2012 and Pediatric Nursing 2015 (**Appendix 5**) and one international meeting (2014 the Pediatric Critical Care World Congress). The manuscript describing our results is attached (**Appendix 6)** and is in review for publication in *Critical Care Medicine.* Our results highlight the importance of a multi-faceted, house-wide education and re-education plan in conjunction with real-time feedback and involvement of the end-users in the development of CDS in order to achieve successful adoption and use of time sensitive CDS.

Future Work:

Specific Aim 1:

1) As described above, final analyses are still underway for our severe sepsis and septic shock cohort. Further, the CHO EPIC IT team is currently still completing the house-wide 2014 EPIC upgrade and will be transitioning to assume the ongoing modifications to, report generation and maintenance of the sepsis BPA and order sets. These activities are to be completed by Spring 2016. As our sepsis initiative has been adopted as standard practice across the institution, Drs. Heidersbach and Mansour will continue to report progress to the CHO Best Practice Committee on a semi-annual basis.
2) The addition of Surviving Sepsis education has been well received as part of our American Heart Association Pediatric Advanced Life Support program. This addition will also remain standard practice at CHO and is being considered for national use by the Pediatric Section of the American Heart Association.

Specific Aim 2:

After meeting with the EPIC programming team in early October 2015, it was decided to discontinue the current BPA for the time being, and to re-introduce it when the above changes have been made. Additionally, the clinicians decided that the traditional “BPA” was not the best for this use. The revised Alerts for 1 and 2 will be an “Alert Banner” positioned in the patient

Overview Report, which is used for rounding on infants daily, along with a new Growth information box below it. The Growth information box will provide information on weight in the previous week, an average for the week, current feeding regimen and links to other information like the infant growth curves. The Banner will be visible whenever the patient's averaged weight over the previous 7 days meets an alert target. The Banner is preferred as it does not require clinicians to take immediate action to stop it, or take extra steps to document a change in feeding regimen. The new anticipated go-live date for alerts 1 and 2 is February 2016.

Regarding the BPA's #3 and #4, the NICU Nutritional "Alert" team feels that their initial design may be the best way to follow growth in NICU babies. We plan to implement the final 2 alerts looking at growth centiles, but due to the complexity of creating this BPA which prevented its use in the initial go-live, and the redo of BPA's 1 and 2, it has not been finalized as yet. EPIC programmers are still working on calculating weight centiles based on term and preterm growth curves in EPIC. Once this has been done successfully, the following additional BPA's will begin:

3. Every Tuesday (the day that the NICU nutritionist rounds with the clinical team), the infant's current weight will be compared with last Tuesday's weight. If the previous weight was above the 25th percentile for growth and current weight has fallen to below the 25th percentile, the BPA will be initiated.
4. Every Tuesday, the infant's current weight will with last Tuesday's weight. If the previous weight was below the 75th percentile, and current weight has crossed above the 75th percentile, the BPA will be initiated.

Future BPA's will also include assessment of length, head circumference and weight for length.

Although the parameters we chose for the initial alerts were not ideal, their implementation had several positive effects which included:

1) increased awareness of the importance of nutrition by the NICU physicians and staff;
2) development of a consistent approach to deal with growth failure, and increased awareness by the NICU physicians and staff of the detrimental effects of over-nutrition.
3) We also began to realize the detrimental effects of alarm fatigue and the need to provide on-going education to all the staff regarding the actions that need to be taken in response to an alarm.

b) We will continue to **educate physician staff** about the new EPIC NICU Nutrition Alert System. The educational program will includes ongoing review of our nutritional goals for the NICU patient population, review of the implemented "Alert" system, suggested responses to enabled "Alerts", and plans for improving the system. Structured education about the nutrition goals continues to be given to all residents at the beginning of their NICU rotation.

- Using methods initiated by the Sepsis team **(Specific Aim 1),** we plan to implement **laminated posters** describing the BPA at each of the resident charting areas in the NICU and the Neonatology Department for easy reference, once the revised programming is implemented.

c) We will continue to **interface with nurse educators and nursing management** for the NICU to enhance didactic education around the implementation of Nutritional "Alerts." Education on the BPA alerts will be included in all EPIC training for new nurses. We will continue to re-evaluate the BPA and educational needs on an annual basis.

d) **Data collection and analysis.** All patients are still being entered into the multi-relational Access database, which was created by Dr. Durand, initial PI for this grant, prior to the implementation of the EHR and maintained by Ms. Asselin. This allows us to continue to collect detailed data on actual nutrition delivered and growth achieved. Resident education, paper clinical guidelines, and nutritional targets remain the same. These outcomes will continue to be analyzed following the implementation of changes in the EPIC Nutritional Alert system. Drs. D'Harlingue, Dudell, Merrill and Flori and Ms. Asselin, are continuing to refine the data analysis plan. We hope that our ability to query EPIC will develop to the point that data will no longer need to be collected from our stand alone database. This will likely be achieved once we are able to order total or partial parenteral nutrition on EPIC. This will improve the efficiency of data collection and allow more frequent analysis. Similarly, this can possibly be further adjusted for application to pediatric patients of all ages across the CHO system, and ultimately to adults and others at other hospital based locations also using the EPIC platform.

Reporting of results:

Specific Aims 1/3:
Within CHO:
Our research work has been presented twice at CHO Grand Rounds since the inception of this grant. From a hospital QI perspective we are pleased to report that our sepsis initiative is being transitioned to standard of care within CHO. Ongoing data analyses will continue to be reported through the Code Blue Committee and the Best Practice Committee.

Nationally:
Our preliminary data has been presented at the 2015 VPS Users Meeting in New Orleans. VPS is a national clinical database dedicated to standardized data sharing and benchmarking among pediatric ICUs (www.myvps.org). Our data has also been presented at the 2015 EPIC Physician Advisory Council meetings in August 2015 in order to enable our CDS platforms to migrate to other users of EPIC nationwide. As described above, the results of our sepsis initiative focus groups (Specific Aim 3) have been presented at two national (Society for Pediatric Research in 2012 – submitted previously - and Pediatric Nursing 2015 (Appendix 5) and one international meeting (2014 the Pediatric Critical Care World Congress – submitted previously).

In addition to the above presentations, we have initiated a presentation and manuscript development subgroup to capitalize on the broad areas of knowledge gained through the last 4 years of this research program. A brief list of manuscripts and expected submissions for presentation to national meetings is listed below.

a. Results of a stepwise clinical decision support strategy to augment understanding and effectiveness of time sensitive identification and management of pediatric severe sepsis

and septic shock – Submitted for publication to the Society for Critical Care Medicine. **Appendix 6**

b. What is the optimal "sensitivity" and "specificity" for alert systems within the Electronic Healthcare Environment? – To be submitted for presentation at the Institute for Healthcare Improvement 2016.
c. Development of the Rapid Response Team for Sepsis in the Emergency Department Environment. – To be submitted to the Pediatric Academic Societies 2016 for presentation.
d. Incorporation of Surviving Sepsis Education within Pediatric Advanced Life Support Certification. This is anticipated to be presented at the Society for Pediatric Research National Conference in May 2016 (**Appendix 7)**
e. Utility of the Healthstream Learning System for Pediatric Severe Sepsis education. To be submitted for presentation at the 2016 Institute for Healthcare Improvement.
f. Engaging Critical Care RNs in Clinical Decision Support: A Pilot Investigation This abstract presented at the 31st Annual Pediatric Nursing Conference on July 9, 2015 in Chicago, Illinois**. (Appendix 5)**
g. Is initial lactate a reliable predictor of outcome in pediatric severe sepsis and septic shock? Accepted for presentation at the 2016 Society for Critical Care Medicine National Conference with manuscript currently in progress. (**Appendix 8)**

<u>Specific Aim 2:</u>
Data from Specific Aim 2 are reported throughout the NICU faculty at present with plans to incorporate these data to a hospital wide platform

Key Research Accomplishments

1) <u>Improved clinical outcomes in pediatric patients with severe sepsis/septic shock.</u> Our data support expansion of our severe sepsis and septic shock early identification tools and management order sets to other institutions offering the EPIC platform at present. Although a single center investigation, our sepsis initiative has endorsed that, although time and labor intensive, a comprehensive, multi-faceted approach can be successfully applied throughout a hospital system to result in tangible improvements in clinical outcomes. Indeed, our data have been presented nationally at the 2015 EPIC Physician Advisory Council meetings this past summer for that expressed purpose. Portability to other EHR systems is still to be determined however this is also the initiative of other national organizations such as The Clinical Decision Support Consortia whose study results of CDS usage in adults has completed enrollment with results pending at this time (Clinical Trials.gov NCT 00853619).
2) Proven methodology to provide *house-wide, successful and sustained* engagement of end users involved in interactive, CDS development with applicability to all healthcare environments.
3) Initiation of *timely, efficient and effective* surviving sepsis education embedded within Pediatric Advanced Life Support training for healthcare professionals.
4) Initiation of time-sensitive, interactive nutrition CDS for critically ill infants.

Reportable Outcomes – none at this time.

Conclusions:

Our concept protocols examine both short-term (minutes to hours) management algorithms **(Specific Aims 1 and 3)** in pediatric severe sepsis/septic shock patients as well as longer term (days) algorithms **(Specific Aim 2)** in critically ill infants with complex nutritional needs. Our outcomes remain relevant both internally and externally in that we seek to improve algorithm compliance as well as key patient morbidities, such as resolution of organ failure and length of stay after shock like states. **(Specific Aim 1)** Successful implementation of the NICU Nutritional Clinical Decision "Alerts" will provide an important tool to the continued assessment of neonatal growth during the NICU stay, and may prove applicable to other critically ill pediatric and adult patients who require long-term hospitalization. **(Specific Aim 2).** Active participation and assessment of our educational efforts **(Specific Aim 3)** has proven that attention to EMR-independent barriers to implementation as well as widespread and multi-faceted education and re-education efforts provide a necessary foundation to successful implementation of CDS embedded within an EHR. These data have been presented internationally. Our "paper based" CDS efforts and broad, multi-faceted educational strategies to date have also *independently* improved algorithm compliance and patient morbidities at our institution.

Our research has been fortunate to attain our initial mission and vision: Given the expansion of the electronic healthcare movement across the world, adequately explicit, time-sensitive clinical decision support (CDS) tools can be developed to help clinicians implement best practice strategies. Although intensive, properly designed and implemented, our *interactive* CDS algorithms for sepsis and nutrition have the potential to save lives and improve morbidity in critically ill children. These prototyped CDS also advance the field of EHR based CDS as most CDS developed to date involves *passive* technology rather than *interactive* CDS.

We are fortunate also that our primary area of investigation, assessment and management of severe sepsis and septic shock, although prototypical for other time sensitive critical illness, is also relevant in and of itself. Indeed, sepsis is the number one killer of adults and children worldwide (www.worldsepsisday.org and www.sepsisalliance.org). Importantly, this algorithm in particular is potentially portable for use *as-is* to other healthcare institutions nationwide and worldwide, and can also be applied to adults with minimal adjustment (ie "trickle upwards and outwards from our single center, pediatric arena).

Further, the methodology developed to create and implement our interactive CDS can be used to develop similar CDS useful for other time-dependent clinical scenarios such as traumatic brain injury, stroke, myocardial infarction, cardiac arrhythmia, multiple organ system failure, etc.

Our work has been favorably received and positively endorsed at every national and international arena presented. This includes the EPIC analyst and leadership teams, the American Heart Association Pediatric Advanced Life Support steering committee, the World Federation of Pediatric Critical Care Surviving Sepsis leadership teams and the Virtual PICU National users groups. We look forward to continuing to transition our work at CHO to standard patient care, to continue to optimize our interactive CDS technology and to continue to analyse our data and present these results at national meetings and in peer reviewed publications in the next years to come.

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Middleton B. *The Clinical Decision Support Consortium.* IOS Press, 2009. p 26-30

Appendices:

Appendix 1: Healthstream Learning Module 2014 September
Appendix 2a: Sepsis Assessment Tool

Appendix 2b: Smart CPG for Sepsis
Appendix 3: ED Sepsis Order Set
Appendix 4: Sepsis BPA Tracking Questionnaire
Appendix 5: Engaging Critical Care RNs in Clinical Decision Support
Appendix 6: Adaptation of the Surviving Sepsis Guidelines in a Tertiary Hospital
Appendix 7: APA Abstract PALS Sepsis
Appendix 8: Initial Lactate as a Predictor of Outcome

Supporting Data: none

Appexdix 1:

Surviving Sepsis Campaign

Time Sensitive
&
Best Practice Care
of Children with Sepsis

What is it?

- The International Surviving Sepsis Campaign (SSC) was created in 2002 and r and includes clinical parameters for hemodynamic support of pediatrics and neonatal shock
- These International Guidelines support the evidence that early detection of infection and institution of antibiotic therapy leads to improved survival

How is this being Implemented here at UBCHO?

- Interdisciplinary Committee formed to update policies and guidelines
- Providing housewide interdisciplinary Education about the diagnosis of Sepsis
- Establishing Reference Tools available for all patient's caregivers
- Coordinating improved "TIME" of Sepsis care now and with Sepsis BPA (Best Practice Advisory) in EPIC

FACTS:

- Severe Sepsis carries a 10-17% overall mortality in children
- Children between 1 and 12 months have the highest mortality (13.5%)
- Treatment guidelines support the evidence that EARLY DETECTION of infection and institution of antibiotic therapy leads to "Improved Survival"

Definitions: A Quick Review

- Bacteremia: A presence of viable bacteria in the blood

- Sepsis: A suspected or proven infection with systemic inflammatory response syndrome (SIRS)

More Definitions:

- Severe Sepsis: Sepsis plus cardiovascular dysfunction or

  ARDS (Acute Respiratory Distress Syndrome) or two or MORE Organ Dysfunctions secondary to infection

- Septic Shock: Severe Sepsis with Hypotension that is NOT reversed with fluid resuscitation

Definitions…
End Organ Dysfunction Criteria

- Lethargy/Irritability/Altered mental status (not just "cranky") OR
- Poor Perfusion (CRT> 3 seconds) OR
- Decreased Urine Output (<0.5ml/kg/hr) OR
- Bilateral Infiltrates on CXR + need for Oxygen

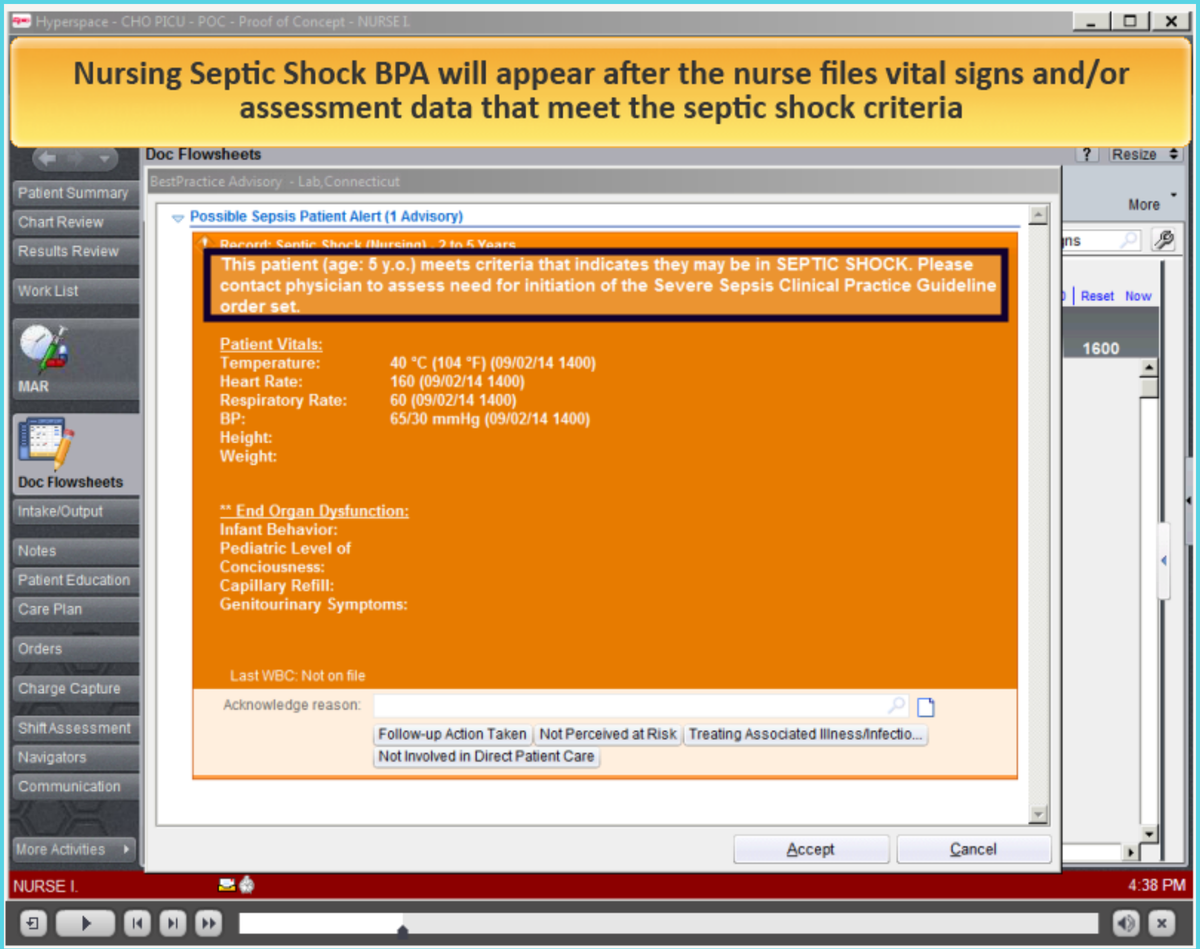
“Three” Tools were Developed

- 1. Severe Sepsis BPA
- 2. Rapid Sepsis Assessment with Age Related Reference for HR, RR, WBC and Systolic BP
- 3. Treatment Guidelines with “TIME” Goals (Severe Sepsis CPG)

Severe Sepsis BPA in EPIC

A Best Practice Advisory will appear on patients whose vital signs or assessment data meets the Severe Sepsis or Septic Shock criteria.

Sepsis BPA


Hyperspace - CHO PICU - POC - Proof of Concept - NURSE I.
Nursing Septic Shock BPA will appear after the nurse files vital signs and/or assessment data that meet the septic shock criteria
Doc Flowsheets
BestPractice Advisory - Lab,Connecticut
Possible Sepsis Patient Alert (1 Advisory)
This patient (age: 5 y.o.) meets criteria that indicates they may be in SEPTIC SHOCK. Please contact physician to assess need for initiation of the Severe Sepsis Clinical Practice Guideline order set.
Patient Vitals:
Temperature: 40 °C (104 °F) (09/02/14 1400)
Heart Rate: 160 (09/02/14 1400)
Respiratory Rate: 60 (09/02/14 1400)
BP: 65/30 mmHg (09/02/14 1400)
Height:
Weight:
** End Organ Dysfunction:
Infant Behavior:
Pediatric Level of Conciousness:
Capillary Refill:
Genitourinary Symptoms:
Last WBC: Not on file
Acknowledge reason:
Follow-up Action Taken
Not Perceived at Risk
Treating Associated Illness/Infectio...
Not Involved in Direct Patient Care
Accept
Cancel
Patient Summary
Chart Review
Results Review
Work List
MAR
Doc Flowsheets
Intake/Output
Notes
Patient Education
Care Plan
Orders
Charge Capture
Shift Assessment
Navigators
Communication
More Activities
Resize
More
Reset
Now
1600
NURSE I.
4:38 PM

Severe Sepsis BPA

What am I suppose to do about this Septic Shock BPA?

NURSING STAFF

1) Call a MedStat
* Document the Medstat events on the code sheet

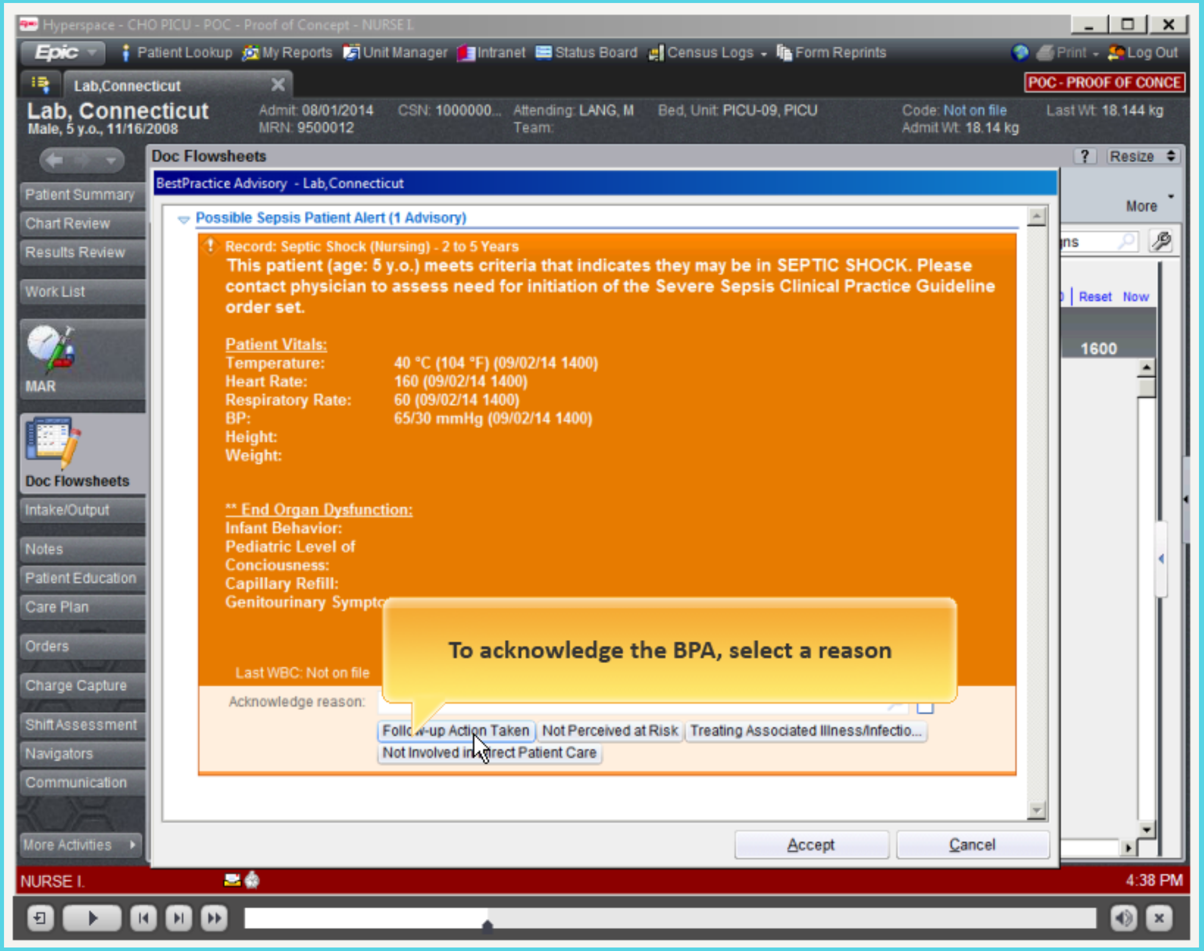
OR

2) Contact the provider STAT
* If the provider placed a Sepsis Order Set, carry out the orders
* Re assess as needed

And

3) Acknowledge the BPA

Severe Sepsis BPA



Sepsis Assessment

- So HOW do I assess for "Sepsis"?
- Consult the Sepsis Guidelines (CPG) and "Rapid Sepsis Assessment Tool" when SUSPECT the potential of sepsis
- These references are located:

  On the Code Carts

  Sepsis Patient Management Plan (on CHONET)
- The TOOLs have age-related assessment references

#1: Rapid Sepsis Assessment Tool

RAPID SEPSIS ASSESSMENT *

For reference only – based on guidelines at Children's Hospital & Research Center Oakland

1

- Two of the following (**one** must be TEMP or WBC):
- Temp >38.5 or < 36
- WBC per table below
- RR - per table below
- HR - per table below
- **IF YES = SIRS (Systemic Inflammatory Response Syndrome)**

2

- Infection suspected?
- **IF YES = SEPSIS**

3

- End Organ Dysfunction? (see criteria below)**
- **IF YES = SEVERE SEPSIS**
- CALL MD (attending physician OR PICU attending or fellow) immediately!
- Consider sending labs and starting ***SEVERE SEPSIS GUIDELINE***

4

- Hypotension?
- **IF YES = SEPTIC SHOCK**
- ***START SEVERE SEPSIS GUIDELINE IMMEDIATELY!***

AGE GROUP	TACHY-CARDIA	BRADY-CARDIA	RESPIRATORY RATE	WBC	SYSTOLIC BP
0 d to 1 wk	> 180	< 100	> 50	> 34	< 65
1 wk - 1mo	> 180	< 100	> 40	> 19.5 or < 5	< 75
1 mo – 24 mo	> 180	< 90	> 34	> 17.5 or < 5	< 100
2 – 5 yrs	> 140	NA	> 22	> 15.5 or < 6	< 94
6 – 12 yrs	> 130	NA	> 18	> 13.5 or < 4.5	< 105
13 - < 18 y	> 110	NA	> 14	> 11 or < 4.5	< 117

** End Organ Dysfunction:

Lethargy/irritability/altered mental status (not just "cranky") OR

Poor perfusion (CRT > 3 secs) OR

Decreased urine output (< 0.5 ml/kg/hr) OR

ANY bilateral infiltrates on CXR + need for oxygen

* Based on **International pediatric sepsis consensus conference: Definitions for sepsis and organ dysfunction in pediatrics** Pediatr Crit Care Med 2005 Vol. 6, No. 1

FIRST: Assess Parameters in Age Related Table

AGE GROUP	TACHYCARDIA	BRADYCARDIA	RR	WBC	SYSTOLIC BP
0 d to 1 wk	> 180	< 100	> 50	> 34	< 65
1 wk - 1mo	> 180	< 100	> 40	> 19.5 or < 5	< 75
1 mo - 1 y	> 180	< 90	> 34	> 17.5 or < 5	< 100
2 – 5 yrs	> 140	NA	> 22	> 15.5 or < 6	< 94
6 – 12 yrs	> 130	NA	> 18	> 13.5 or < 4.5	< 105
13 - < 18 y	> 110	NA	> 14	> 11 or < 4.5	< 117

Rapid Sepsis Assessment:

- Does your patient have "TWO" of the following? (one MUST be TEMP or WBC)
- Parameters Per Age:

  Temp >38.5 or <36

  WBC per Table (Elevated OR Low)

  RR per Table (Tachypnea)

  HR per Table (Tachycardia OR Bradycardia)

IF YES=SIRS (Systemic Inflammatory Response Syndrome)…

Patient Example:

- Your Patient is:
- 5 years of age
- Temp 39
- HR of 155
- RR of 32
- WBC of 20

AGE GROUP	TACHYCARDIA	BRADYCARDIA	RR	WBC	SYSTOLIC BP
2 – 5 yrs	> 140	NA	> 22	> 15.5 or < 6	< 94

So you have identified that your patient
Has "TWO" out of range parameters
AND…Meets criteria of ONE Parameter = Temp Elevation AND/OR Elevated WBC

Is it Sepsis?

- Is an Infection Suspected? If YES=Sepsis
- IS There "END Organ Dysfunction"?
- Lethargy/Irritability/Altered Mental Status (not just cranky) OR
- Poor Perfusion (CRT>3 seconds) OR
- Decreased Urine Output (<0.5ml/kg/hr)
- ANY Bilateral Infiltrates on CXR + Need for Oxygen?
- IF YES=SEVERE Sepsis

Follow the "Severe Sepsis" Guidelines:

CHILDREN'S HOSPITAL & RESEARCH CENTER OAKLAND – SEVERE SEPSIS CPG

These guidelines are used at Children's Hospital & Research Center Oakland and are provided as a reference.*

CHRCO TRANSFER CENTER (855) 246-5437

Time Zero**

1) **Concern for shock**-Besides fever, tachycardia, and hypotension, some patients present initially only with altered mental status and decreased perfusion (delayed or flash capillary refill) – **REFER TO RAPID SEPSIS ASSESSMENT TOOL!**
2) Call **Medstat**.
3) Place **oxygen** on all patients!
4) Initiate attempts at **IV access** and **lab testing (OK to use Broviac/central line)**:
(**POC** tests-blood gas, glucose, lytes, lactate. Also CBC, chem 8, blood cultures)
5) Know where **IO** equipment is!

0-15 Minutes – START!

1) If no IV access by 5 minutes, **consider IO!**
2) **PUSH** fluids (isotonic crystalloid) *by hand* over 5 minutes if possible, not on a pump, 20 ml/kg IV, repeat until perfusion improves unless rales or hepatomegaly develop, maximum 60 ml/kg IV .
(Fluid resuscitation will take longer than 15 minutes, but initiate here!)
3) Assess **point of care** results and **treat hypoglycemia and hypocalcemia**
4) Order **antibiotics** and give ASAP (Goal for first dose to be in by 30 minutes!)
5) Order **inotropes** to bedside, use if BP low *and* 2nd IV available, MAY give inotropes through PIV or IO, even on the ward!
(Dopamine 5-10 mcg/kg/min or epinephrine 0.05-0.3 mcg/kg/min)

15-60 Minutes – REASSESS!

1) Consider **hydrocortisone** for adrenal insufficiency! (25 mg IV under 6 months, 50 mg IV up to 9 years, 100 mg IV if 10 years or older)
2) Reconsider need for **inotropes** if not already being given.
3) Reassess:
   - A) Appropriate **cultures** have been drawn,
   - B) **Antibiotics** given, and
   - C) Sufficient **fluid resuscitation** given

1-4 Hours (Even if not yet in PICU)

If blood pressure is *not* normalized, tachycardia is *not* resolved, or still needs inotropes;

1) Consider need for more **fluid boluses** (up to 200 ml/kg).
2) Consider adjusting **inotropes** upwards or adding vasopressors (norepinephrine or vasopressin).
3) May need **blood transfusion.**
   (Surviving Sepsis Guidelines suggest goal Hgb 10)
4) Consider **pericardial effusion**, **pneumothorax**, and **increased intra-abdominal pressure**. Treat if found.
5) May require **central line** for access and/or monitoring.
6) Consider repeat POC blood gas with lytes and glucose.

** **Time zero** is the first point at which anyone considers that a child might be septic. Other times are given as ranges with the idea that every point will have been initiated, or at least considered, by the end of the time frame.

* Based on Surviving Sepsis Campaign Guidelines: Intensive Care Med (2008) 34:17–60, No.3; www.survivingsepsis.org

Treatment Guidelines to Implement NOW

- Notify MD (attending physician OR PICU attending or fellow) Immediately!
- Team should implement SEVERE SEPSIS GUIDELINE
- CALL a Med Stat for Team Assist ASAP

  on acute care units to get the HELP needed…This is “TIME ZERO”

TIME ZERO: "TIME" of First Point at which Severe Sepsis is "Suspected"

- Call Med Stat when Severe Sepsis Identified
- DO NOT HESITATE!
- Refer to Rapid Asessment Tool

TIME ZERO Actions…

- Place Oxygen on ALL patients
- Initiate attempts at IV access
- Lab Testing:

  *POC: Blood Glucose, Blood Gas, Lytes, Lactate

  *CBC, Chem 8, Blood Cultures

TIME ZERO Actions…

- KNOW there is IO (Intraosseus) equipment on the Crash Cart if cannot easily establish IV Access
- Rapid Response Team will bring the EZIO

EZIO Facts:

- Usually placed in anterior tibia
- They almost never cause infections or broken bones
- They DO Infiltrate
- Establish QUICK Intravenous Access

0-15 Minute Patient Care ACTION's:

- If NOT IV access by 5 minutes, consider placing intraosseus line
- CAN Use Broviac or other Central Line
- Initiate PUSH of clear IVF that increase circulating volume (Isotonic Crystalloid) by hand over 5 minutes

(CAN PUSH IV Resuscitation Fluids on AC Units)

*DO NOT use Pump

*20ml/kg to start

*Repeat until perfusion improves

*Maximum of 60ml/kg IV within 1st 15 minutes of Severe Sepsis Guideline

0-15 minutes Patient Care ACTION's….

- Assess Point of Care (POC) results
- Treat hypoglycemia and hypocalcemia
- Administer Ordered Antibiotics and give ASAP
- GOAL: First dose to be IN by 30 minutes
- The MED STAT Pharmacy team will be RUNNING to bring them to you!

0-15 Minute Patient Care Actions…

- What about Vasoactive Medications?

(Inotropes=Meds that increase heart function)

- Recommended:

  Dopamine 5-10 mcg/kg/min OR

  Epinephrine=0.05-0.3 mcg/kg/min

- Consider them!!! CAN be given before patient get's to PICU!
- Can give Inotropes through PIV or IO or Central Lines!
- Can be given on the Acute Care Units!
- Remember… the Rapid Response Team will be there on the Acute Care Units…..

15-60 Minute Patient Care Actions…

- Can Give Additional Fluid Boluses if patient with:
  - *Delayed Capillary Refill
  - *Hypotension
  - *Tachycardia

Patient's OFTEN need 60ml/kg or more!

Give MORE to normalize heart rate and perfusion

15-60 Minute Patient Care Actions...

- May administer hydrocortisone for Adrenal Insufficiency
- Reconsider Inotropes if not already being given
- Reassess that appropriate cultures have been drawn... antibiotics given and sufficient fluid resuscitation (up to 100ml/kg...sometimes MORE!)

1-4 Hours if NOT in the PICU....Patient Care Actions Might Include:

- IF blood pressure NOT normalized and tachycardia NOT resolved, perfusion is not improved.....
- Can consider fluid up to 200ml/kg IV
- Can adjust Inotropes upwards OR add vasopressors (Norepinephrine, Vasopressin)
- May need Blood Transfusion

1-4 Hours of Patient Care Actions… IF NOT in the PICU

- Assess for and treat if found:
  - Pericardial Effusion
  - Pneumothorax
  - Increased intra-adominal pressure

To Review…

- KNOW the location of the following on your unit:
  - Rapid Sepsis Assessment Tool
  - Severe Sepsis Guideline (CPG)
- REMEMBER that "TIME ZERO" is the first point at which anyone considers that a child might be septic

Appendix 2a:

RAPID SEPSIS ASSESSMENT *

For reference only – based on guidelines at Children's Hospital & Research Center Oakland

1

- Two of the following (**one** must be TEMP or WBC):
- Temp >38.5 or < 36
- WBC per table below
- RR - per table below
- HR - per table below
- IF YES = SIRS **(Systemic Inflammatory Response Syndrome)**

2

- Infection suspected?
- IF YES = SEPSIS

3

- End Organ Dysfunction? (see criteria below)**
- IF YES = SEVERE SEPSIS
- CALL MD (attending physician OR PICU attending or fellow) immediately!
- Consider sending labs and starting ***SEVERE SEPSIS GUIDELINE***

4

- Hypotension?
- IF YES = SEPTIC SHOCK
- ***START SEVERE SEPSIS GUIDELINE IMMEDIATELY!***

AGE GROUP	TACHY-CARDIA	BRADY-CARDIA	RESPIRATORY RATE	WBC	SYSTOLIC BP
0 d to 1 wk	> 180	< 100	> 50	> 34	< 65
1 wk - 1mo	> 180	< 100	> 40	> 19.5 or < 5	< 75
1 mo – 24 mo	> 180	< 90	> 34	> 17.5 or < 5	< 100
2 – 5 yrs	> 140	NA	> 22	> 15.5 or < 6	< 94
6 – 12 yrs	> 130	NA	> 18	> 13.5 or < 4.5	< 105
13 - < 18 y	> 110	NA	> 14	> 11 or < 4.5	< 117

** End Organ Dysfunction:

Lethargy/irritability/altered mental status (not just "cranky") OR

Poor perfusion (CRT > 3 secs) OR

Decreased urine output (< 0.5 ml/kg/hr) OR

ANY bilateral infiltrates on CXR + need for oxygen

* Based on **International pediatric sepsis consensus conference: Definitions for sepsis and organ dysfunction in pediatrics** Pediatr Crit Care Med 2005 Vol. 6, No. 1

Appendix 2b:

CHILDREN'S HOSPITAL & RESEARCH CENTER OAKLAND – SEVERE SEPSIS CPG

These guidelines are used at Children's Hospital & Research Center Oakland and are provided as a reference.*

Time Zero**

1) **Concern for shock**-Besides fever, tachycardia, and hypotension, some patients present initially only with altered mental status and decreased perfusion (delayed or flash capillary refill) – **REFER TO RAPID SEPSIS ASSESSMENT TOOL!**
2) Call **Medstat**.
3) Place **oxygen** on all patients!
4) Initiate attempts at **IV access** and **lab testing (OK to use Broviac/central line)**:
(**POC** tests-blood gas, glucose, lytes, lactate. Also CBC, chem 8, blood cultures)
5) Know where **IO** equipment is!

0-15 Minutes – START!

1) If no IV access by 5 minutes, **consider IO!**
2) **PUSH** fluids (isotonic crystalloid) *by hand* over 5 minutes if possible, not on a pump, 20 ml/kg IV, repeat until perfusion improves unless rales or hepatomegaly develop, maximum 60 ml/kg IV .
(Fluid resuscitation will take longer than 15 minutes, but initiate here!)
3) Assess **point of care** results and **treat hypoglycemia and hypocalcemia**
4) Order **antibiotics** and give ASAP (Goal for first dose to be in by 30 minutes!)
5) Order **inotropes** to bedside, use if BP low *and* 2nd IV available, MAY give inotropes through PIV or IO, even on the ward!
(Dopamine 5-10 mcg/kg/min or epinephrine 0.05-0.3 mcg/kg/min)

15-60 Minutes – REASSESS!

1) Consider **hydrocortisone** for adrenal insufficiency! (25 mg IV under 6 months, 50 mg IV up to 9 years, 100 mg IV if 10 years or older)
2) Reconsider need for **inotropes** if not already being given.
3) Reassess:
    A) Appropriate **cultures** have been drawn,
    B) **Antibiotics** given, and
    C) Sufficient **fluid resuscitation** given

1-4 Hours (Even if not yet in PICU)

If blood pressure is *not* normalized, tachycardia is *not* resolved, or still needs inotropes;

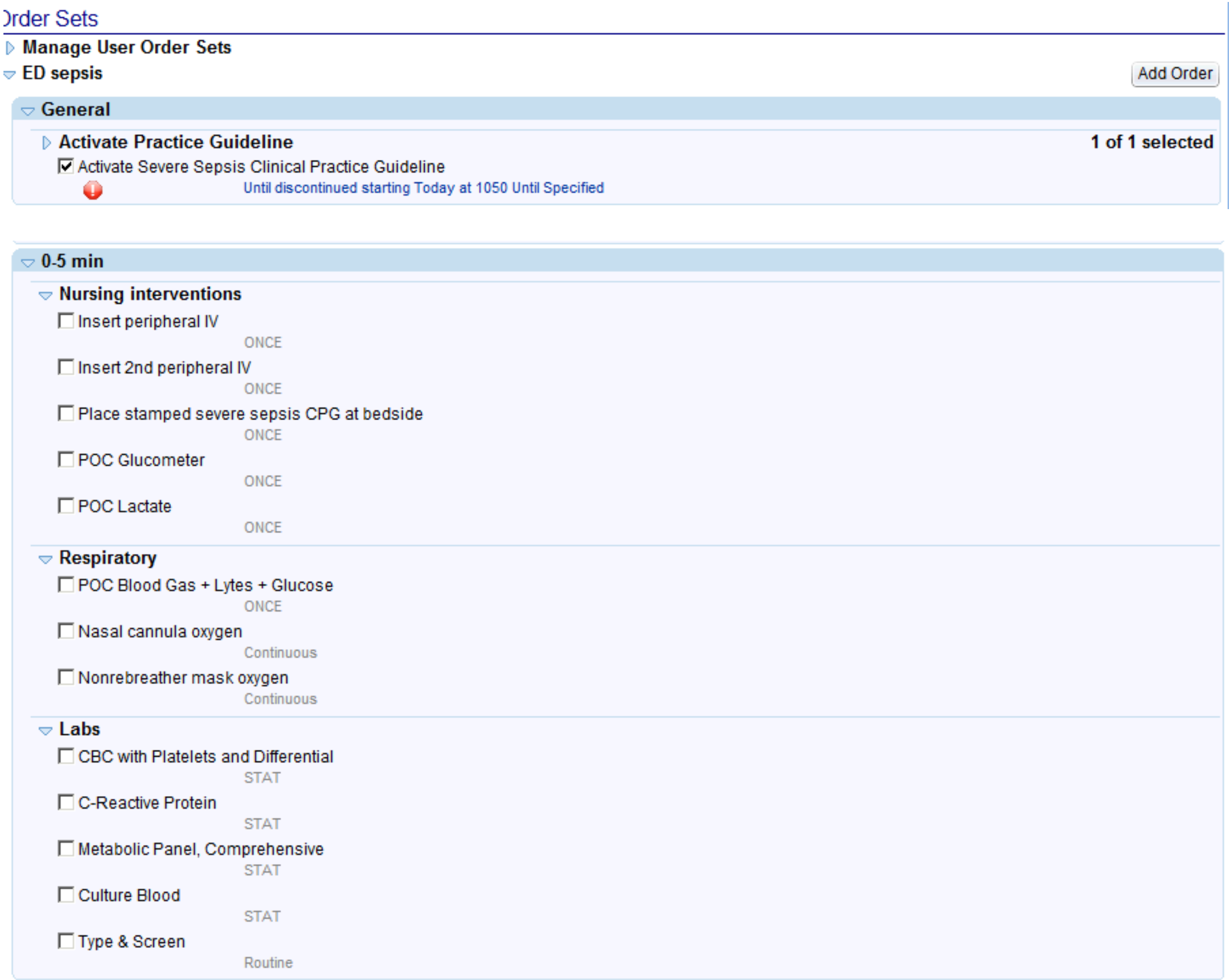
1) Consider need for more **fluid boluses** (up to 200 ml/kg).
2) Consider adjusting **inotropes** upwards or adding vasopressors (norepinephrine or vasopressin).
3) May need **blood transfusion.**
   (Surviving Sepsis Guidelines suggest goal Hgb 10)
4) Consider **pericardial effusion**, **pneumothorax**, and **increased intra-abdominal pressure**. Treat if found.
5) May require **central line** for access and/or monitoring.
6) Consider repeat POC blood gas with lytes and glucose.

** **Time zero** is the first point at which anyone considers that a child might be septic. Other times are given as ranges with the idea that every point will have been initiated, or at least considered, by the end of the time frame.

* Based on Surviving Sepsis Campaign Guidelines: Intensive Care Med (2008) 34:17–60, No.3; www.survivingsepsis.org

Version 4-24-12

Appendix 3: Example Order Set



Appendix 3: Example Order Set

5-15 min

IV Fluid Boluses-Repeat until perfusion improves, or if rales or hepatomegaly develop. (maximum 60 ml/kg over 15 min)

Repeat NS bolus until perfusion improves, or if rales or hepatomegaly develop. Maximum 60 mL/kg over 15 min.
Correct hypoglycemia with D10W if glucose < 40 mg/dL in neonate, or <50 mg/dL in all other ages.

- ☐ sodium chloride 0.9 % (NS) IV Bolus #1
  20 mL/kg, Intravenous, for 5 Minutes, Once, Bolus #1. Give by rapid IV push over 5 minutes.
- ☐ sodium chloride 0.9 % (NS) IV Bolus #2
  20 mL/kg, Intravenous, for 5 Minutes, Once, Bolus #2. Give by rapid IV push over 5 minutes.
- ☐ sodium chloride 0.9 % (NS) IV Bolus #3
  20 mL/kg, Intravenous, for 5 Minutes, Once, Bolus #3. Give by rapid IV push over 5 minutes.
- ☐ dextrose 10 % (D10W) IV "CORRECT HYPOGLYCEMIA"
  5 mL/kg, Intravenous, Once

Antibiotics

Community Acquired: ceftriaxone, vancomycin
Oncology BMT Patients: meropenem, vancomycin, tobramycin

- ☐ cefTRIAXone (ROCEPHIN) IV
  50 mg/kg, Intravenous, Once
- ☐ vancomycin (VANCOCIN) IV
  15 mg/kg, Intravenous, Once Indications: Sepsis Syndrome
- ☐ meropenem (MERREM) IV
  40 mg/kg, Intravenous, Once Indications: Severe Sepsis
- ☐ tobramycin (NEBCIN) IV
  2.5 mg/kg, Intravenous, Once Indications: Sepsis Syndrome

Labs

- ☐ Urinalysis with Microscopy
  STAT
- ☐ Urinalysis with Microscopy
  STAT

Imaging

- ☐ XR Chest 1 View
  STAT, 1 time imaging, Starting 9/29/14
- ☐ XR Chest 2 Views
  STAT, 1 time imaging, Starting 9/29/14

15-60 min

Infusions / Drips - Cardiovascular

- ☐ DOPamine IV drip
  5 mcg/kg/min, Intravenous, Continuous
- ☐ EPINEPHrine (ADRENALIN) IV drip
  0.05 mcg/kg/min, Intravenous, Continuous
- ☐ NORepinephrine (LEVOPHED) IV drip
  0.05 mcg/kg/min, Intravenous, Continuous

IV Fluid

- ☐ dextrose 5 % and sodium chloride 0.45 % (D5 1/2 NS) IV
  Intravenous, Continuous

Labs

- ☐ ETT Culture (if intubated)
  STAT, Endotracheal Tube

60+ min

Anti-Inflammatory - Steroidal

For adrenal insufficiency.

- ☐ hydrocortisone sodium succinate (SOLU-CORTEF) injection (patient age <6 months)
  25 mg, Intravenous, Once
- ☐ hydrocortisone sodium succinate (SOLU-CORTEF) injection (patient age 6 months - 9 years)
  50 mg, Intravenous, Once
- ☐ hydrocortisone sodium succinate (SOLU-CORTEF) injection (patient age >10 years)
  100 mg, Intravenous, Once

Admission

Admission

0 of 1 selected

Appendix 4:

Severe Sepsis/Shock BPA Tracking Evaluation

Date of alert: Patient alerted on:
MRN:

MD alerted:
MD is: resident/fellow/attending

RN alerted:

Patient location: Medical Ward, Heme Onc Ward, ED, ICU, Day Hospital, Surgical Ward

For all:
1) We have a report that you received a Sepsis BPA alert on soandso patient. Is that true? Yes No

2) Was this a "reasonable" alert on this patient? ("Reasonable" here means if this BPA popup was reasonably appropriate to see on this patient at that time. This is a chance also to determine if the alert was too frequent or annoying, but leave it open enough for the responder to give us genuine feedback.)

If yes, why? ____
If no, why? ____

3) Did you understand the 4 options you had to respond to the alert? YES NO
Are they adequately explicit or should the wording change?
YES
NO – HOW? ____

4) What did you choose to do?
____

5) **For docs –**
Do you understand how to access the sepsis order set from the BPA?
Do you understand your choices once you access the order set?

5) **For nurses –**
If you contacted the doctor, did you get the response you wanted?
YES NO

Did you know you could initiate a Med Stat at any time if you were concerned about this patient's course/deterioration? YES NO

Appendix 5:

UCSF Benioff Children's Hospital Oakland

Engaging Critical Care RNs in Clinical Decision Support: A Pilot investigation in Pediatric Septic Shock Patients

Heidi Flori, MD[1]; Karim Mansour, MD[1]; Bella Doshi, MD[1]; Jennifer Plant, MD[1;] Erin Silva, MSN, RN, FNP[1], Reena Palacio, RN[1] and Scott Heidersbach, MD[1]
[1][UCSF Benioff Children's Hospital Oakland], [2][UC Davis Children's Hospital]

BACKGROUND

Severe sepsis is a major cause of mortality in the U.S with mortality rates exceeding those for acute myocardial infarction and common cancers[1]

-Every three heartbeats, someone dies of sepsis

-In the developing world, sepsis accounts for 60-80% of childhood deaths[2]

New recommendations suggest that septic shock be addressed at the institutional level rather than the practitioner level (reference). It's recommended that each institution implement:

1.Recognition bundle containing a trigger tool for rapid identification of patients with suspected septic shock

2.Resuscitation and stabilization bundle to drive adherence to consensus best practice

3.Performance bundle to monitor, improve, and sustain adherence to that best practice

In this study a severe sepsis best practice alert (BPA) was created to alert nurses and physicians that a patient meets specific criteria in the Surviving Sepsis Guidelines that they are at risk or are currently in sepsis. Improving compliance with established Children's Hospital Oakland Management of Septic Shock Guidelines is expected to:

- Decrease time to the reversal of shock
- Decrease the duration of respiratory support
- Decrease the duration of vasoactive medication administration
- Decrease the incidence of multiple organ system failure

Nursing played a vital role in the implementation of this study by:

✓Working with an interdisciplinary team to design an alert that would be clear, concise and easily recognizable by nurses and MDs

✓Ensuring that the alert triggered for the right patient, at the right time and was appropriate

✓Educating nurses to use the alert to guide their next steps in the treatment of sepsis

Figure 1. Severe Sepsis CPG

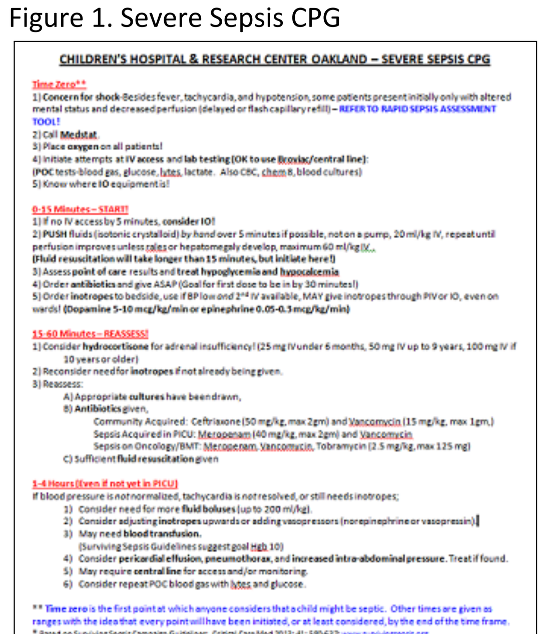
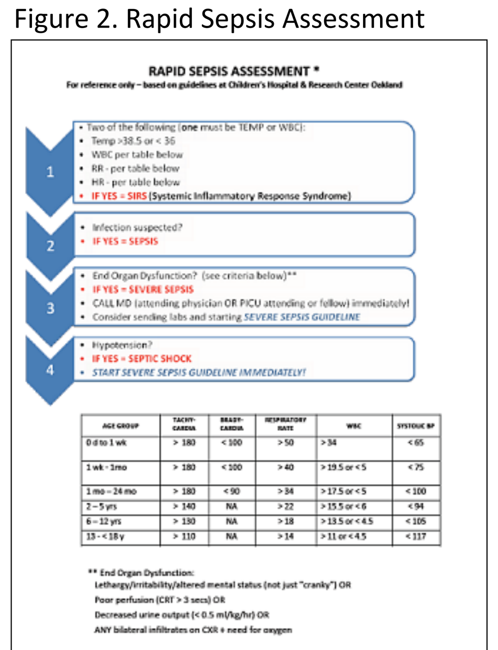


Figure 2. Rapid Sepsis Assessment



METHODS

- Hospital wide education
  - ✓ Large and small group education (in person, web based)
  - ✓ Hands on workshops
  - ✓ Laminated badge cards
  - ✓ Patient safety fair and skills day seminars
- Unit specific education
  - ✓ Weekly BPA fire reports
    - Severe shock/sepsis tracking evaluations
  - ✓ Just-in-time training with each nurse
    - Do they understand the alert?
    - Is the alert appropriate?
    - Do they know what next steps should be taken?
    - Education regarding the treatment of sepsis
- Formation of a workgroup (nurses and physicians)
  - ✓ Feedback and suggestions on the design of the BPA

Figure 3. Sepsis BPA

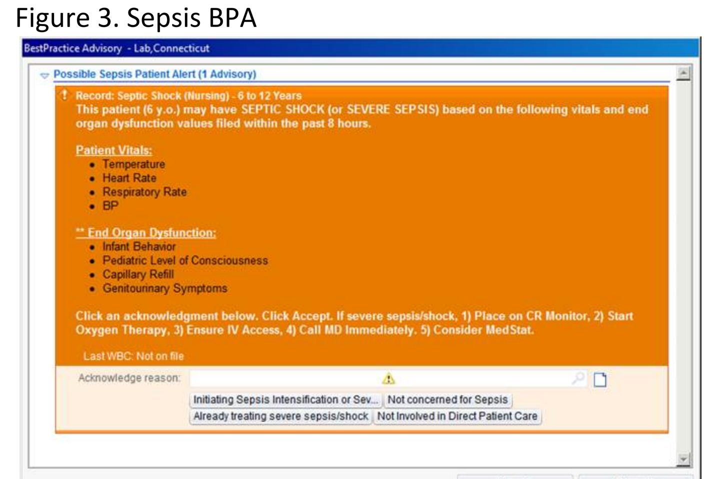


Figure 4. Weekly BPA Fire Report

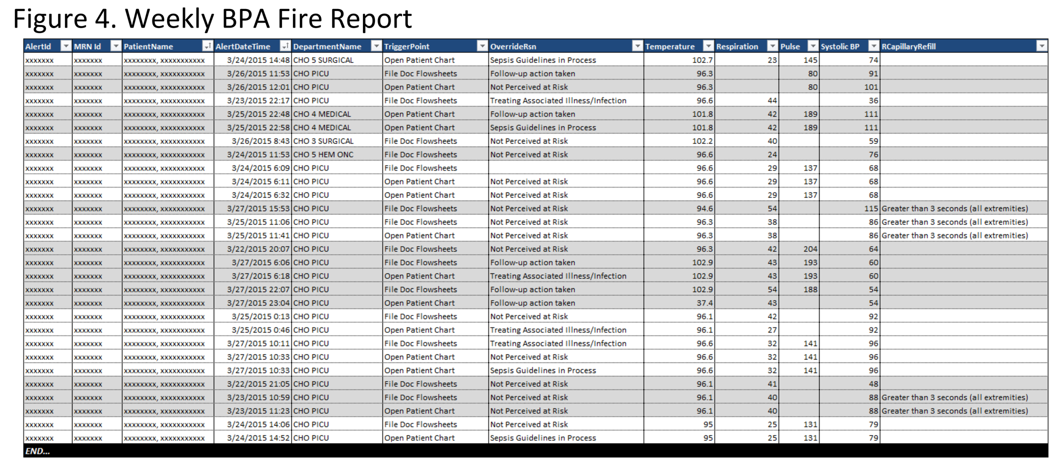
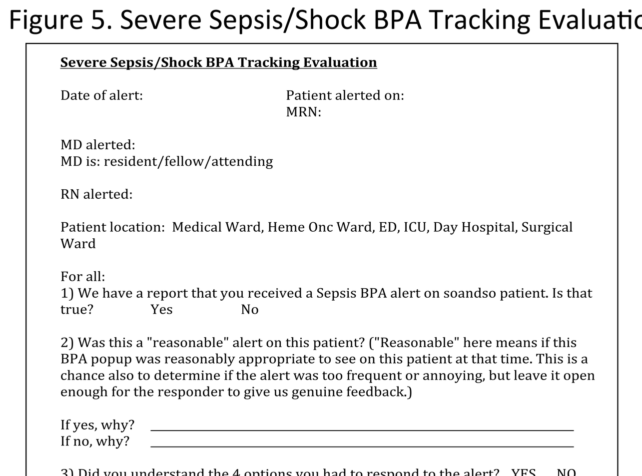


Figure 5. Severe Sepsis/Shock BPA Tracking Evaluation



CHALLENGES

- Educating each nurse about the alert and appropriate sepsis interventions
- Designing the alert so that it fired appropriately and did not contribute to alert fatigue

DATA

- 1,678 Sepsis BPA triggers for 193 unique patients from January 1, 2015 – May 9, 2015

Figure 6. Total Sepsis BPA Alerts

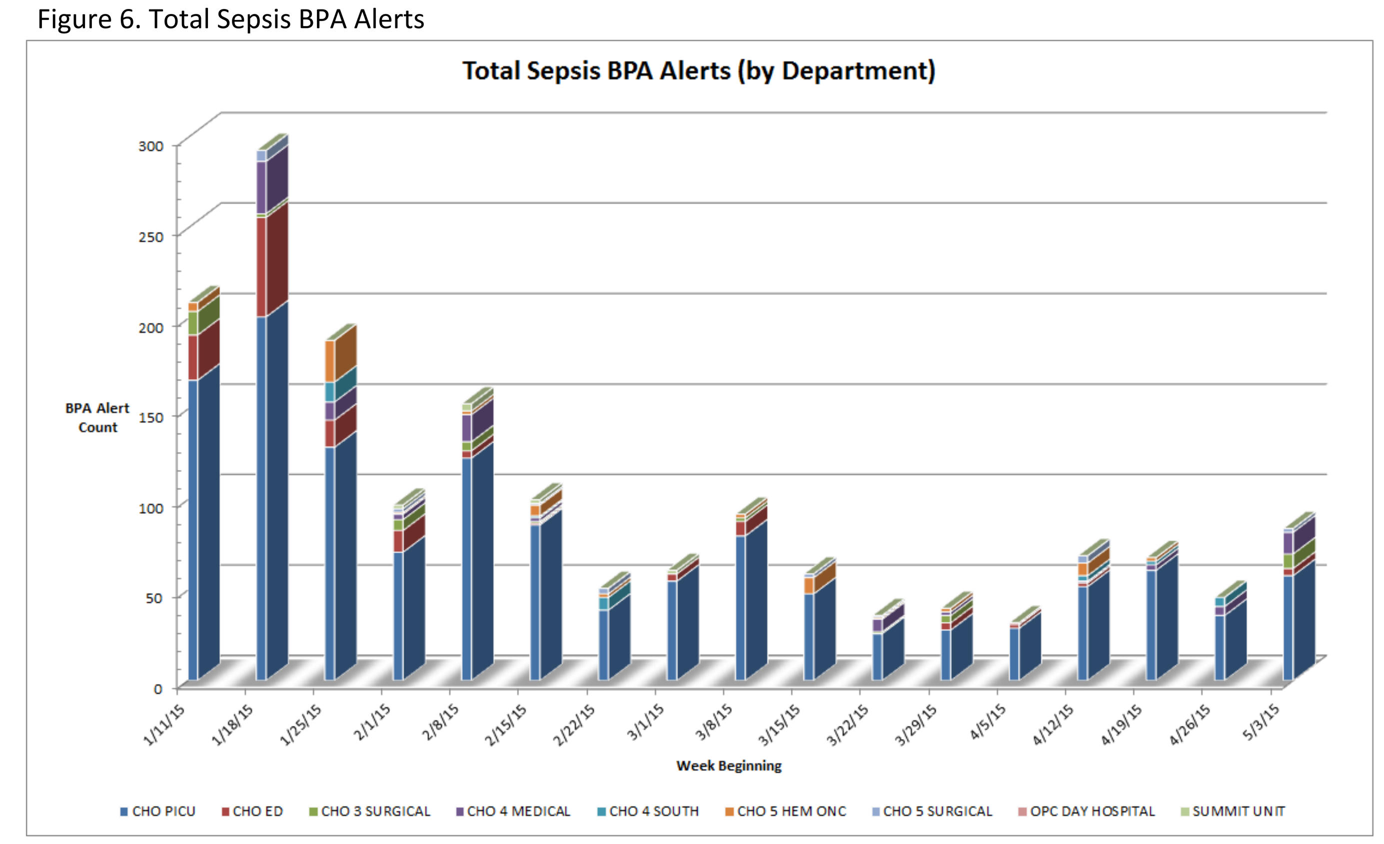


Figure 7. BPA Trigger Data

Overall BPAs by Dept

Department	Count
CHO 3 SURGICAL	42
CHO 4 MEDICAL	89
CHO 4 SOUTH	29
CHO 5 HEM ONC	62
CHO 5 SURGICAL	21
CHO ED	136
CHO PICU	1,288
OPC DAY HOSPITAL	1
SUMMIT UNIT	10
Total	**1,678**

BPA Acknowledge Reasons (by Provider Type)

Provider Type / Acknowledge Reason	Count
Nursing	**806**
**** No Acknowlege Reason Captured (likely cancelled) ****	*299*
Follow-up action taken	127
Not Involved in Direct Patient Care	19
Not Perceived at Risk	171
Treating Associated Illness/Infection	190
Provider	**872**
**** No Acknowlege Reason Captured (likely cancelled) ****	*413*
Follow-up action taken	112
Not Perceived at Risk	127
Not the Primary Provider	55
Sepsis Guidelines in Process	57
Treating Associated Illness/Infection	108
Total	**1,678**

Order Set Opened from BPA (by Dept)

Department	Count
CHO 3 SURGICAL	4
CHO 4 MEDICAL	4
CHO 4 SOUTH	2
CHO 5 HEM ONC	4
CHO 5 SURGICAL	3
CHO ED	12
CHO PICU	61
Total	**90**

SUMMARY OF FINDINGS

- There have been # patients with sepsis identified via the BPA
- Nurses in the PICU, ED and acute units have been trained on the SSC BPG and the BPA
- Education needs to be provided continuously through many different avenues
- Nurses are especially responsive to one-on-one just-in-time training
- Nurses tend to retain interest and stay involved in a practice change when they are engaged with facilitation of the actual work

CONCLUSIONS and FUTURE PLANS??

- Plan to roll out revised version of BPA and continue with weekly BPA reports and interviews
- Form a work group to receive feedback from RNs and MDs regarding revised BPA version
- Overall improvement in recognition and treatment of severe sepsis hospital wide
- RN staff now agree that SSC CPG can improve RN confidence in management of septic patients and communication
- Concern for alert fatigue when assessment tool embedded into EMR
- Still room for improved implementation. Need for culture change
- Hierarchy in medicine can lead to delays in care
- Stigma associated with Rapid Response team activation
- Continued delays due to lack of personnel, difficulty in finding paper, assessment tools and equipment, hesitancy to push fluid and start IOs
- Need for ongoing education with multiple and broader strategies due to greater number and turnover of nurses compared to physicians

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1. Seymour CW, Rea TD, Kahn JM, Walkey AJ, Yealy DM, Angus DC: Severe sepsis in pre-hospital emergency care: analysis of incidence, care, and outcome. Am J Respir Crit Care Med 2012, 186(12):1264-1271
2. Kissoon N, Carcillo JA, Espinosa V, Argent A, Devictor D, Madden M, Singhi S, van der Voort E, Latour J: World Federation of Pediatric Intensive Care and Critical Care Societies: Global Sepsis Initiative. Pediatr Crit Care Med 2011, 12(5):494-503

DISCLOSURES

This study was supported by a grant from the Department of Defense (Grant #USAMRMC W81XWH-10-01-0682) and in part by the CHRCO Neonatal Pediatric Research Group. The terms of this arrangement have been reviewed and approved by UCSF Benioff Children's Hospital Oakland in accordance with its conflict of interest policy.

For additional information please contact:
Erin Silva, MSN, RN, FNP
PICU Nurse Educator and Transportation Coordinator
UCSF Benioff Children's Hospital Oakland
ersilva@mail.cho.org

Appendix 6:

Adaptation of the Surviving Sepsis Guidelines in a Tertiary-Care Pediatric Hospital:

A Method of Complying with the Mandate to Develop an Assessment Tool, Management Plan, and Metric to Track Compliance for the Treatment of Sepsis

R. Scott Heidersbach MD[1], H Flori[2], J Plant[3] [1] UCSF Benioff Childrens Hospital Oakland, California, [2] C.S Mott Children's Hospital, Michigan, [3] UC Davis Medical Center, California

Abstract:

Objective: To evaluate the factors that influence provider compliance with the surviving sepsis guidelines, use a modified Delphi technique to develop a Sepsis Assessment Tool (SAT) and Sepsis Clinical Practice Guideline (sepsis CPG), educate providers, and initiate use of the SAT and Sepsis CPG *prior to* implementation of and incorporation into the EHR.

Design: The study utilized qualitative methods and a modified Delphi technique and is part of a larger study examining the effect of CDS within an EHR on compliance in treating children with severe sepsis or septic shock.

Setting: The study took place at a tertiary care free standing children's hospital over a five year period of time.

Subjects: A convenience sample of physicians and nurses most likely to care for patients with sepsis participated in interviews and focus groups.

Interventions: Investigators facilitated semi-structured interviews and focus groups with physicians and nurses to assess preexisting knowledge of the SSG and determine anticipated and experienced barriers to implementing the SSG. Investigators independently coded and analyzed the transcripts for themes and reconciled themes by consensus discussion. A Modified Delphi technique [1] was used to develop the SAT and Sepsis CPG. Utilizing the themes from the interviews and focus groups, two investigators proposed a SAT and Sepsis CPG. The SAT and CPG were distributed and investigators provided extensive physician and nursing education. Investigators then facilitated another round of interviews and focus groups in order to assess the effects of the educational efforts and their early experiences using the SAT and Sepsis CPG. Two investigators independently coded and analyzed the transcripts for themes and then reconciled themes by consensus discussion.

Measurements and Main Results: 7 physicians and 8 nurses participated in the first round of interviews and focus groups. 7 physicians and 10 nurses participated in the second round of interviews. At the time of the first interviews and focus groups, physicians and nurses agreed that it is challenging to identify severe sepsis and shock and they identified a number of barriers to timely treatment including lack of personnel, lack of resources, inability to obtain intravenous (IV) access, hesitation to provide rapid boluses of intravenous fluids, and a hesitation to start vasoactive infusions through peripheral access. Both groups also saw the potential utility of a sepsis assessment tool and hospital-specific clinical

practice guidelines. With the second set of interviews and focus groups, which took place after the development and implementation of the SAT and Sepsis CPG and the initial educational efforts, both the physicians and nurses felt the new tools were being used throughout the hospital and that there was more timely awareness and treatment of early sepsis and shock. Both groups, however, identified ongoing concerns and areas for improvement. Physicians expressed significant concern that the tools were too sensitive resulting in false positive identifications. Nurses identified additional barriers inherent in the culture of their hospital, namely the hierarchy of medicine and a stigma for nurses calling for extra help with a hospital-wide “med stat” activation, would lead to ongoing delays. Both groups, especially the nurses, felt a need for ongoing education including simulation-based training.

Conclusions: While many of the discovered barriers to implementation of a sepsis CPG were addressed during the development of the paper-based SAT and CPG, only the barriers of recognizing septic patients and access to the CPG and associated order entry will be addressed by the addition of CDS. Other remaining barriers will need to be addressed via other mechanisms such as ongoing education incorporating hands-on training and performance feedback.

Introduction:

There is a Federal mandate to convert all of U.S. medicine to the use of Electronic Health Records (EHRs) with the goal of providing better quality, safety, and coordination of care [2]. The benefits of utilizing an EHR include: improved efficiency and quality of documentation [3], reduction of drug errors [4-7], easier transfer and sharing of records amongst health care workers, and potentially decreased costs [8]. Despite these many potential and realized benefits, there are limits to the utility of EHR systems. EHR systems that are implemented without adequate preparation can have adverse consequences due to changes to workflow and work disruption [2]. In one published case, initiation of computerized physician order entry in a tertiary-care children’s hospital was associated with an increase in mortality [9]. There is a recognized need for robust, randomized clinical trials examining the relationship between quality of care and EHRs [10].

One important focus of such research should be the effect of EHRs incorporating clinical decision support (CDS) on compliance with clinical practice guidelines (CPGs). Clinical Decision Support is any system that parses data in an attempt to provide health workers with additional information to make better clinical decisions for their patients in order to improve outcomes[11, 12]. Despite sound reasoning and evidence behind CPGs, provider compliance with the guidelines is limited by a number of factors including lack of familiarity or awareness, disagreement with the guidelines, lack of self-efficacy or motivation, and external factors such as lack of time or resources [13]. Clinical decision support can be incorporated into EHRs to trigger and guide providers through CPGs, thereby addressing the compliance issues related to difficulty in recognition of a condition or lack of knowledge of the guidelines. CDS tools can be used to support diagnostic decision-making, remind providers about preventative care measures and outline protocols or bundles for disease management[12] and use of CDS within EHRs has been showed to improve compliance with stated guidelines for otitis media

treatment in children [11], to optimize antibiotic use in community acquired pneumonia [14], to improve blood pressure control in the outpatient setting [15], and to enhance treatment of neuropathic pain [16].

Clinical decision support for CPGs has the potential to play a significant role for time sensitive interventions for conditions such as sepsis but this potential has yet to be fully utilized. There is increasing awareness and abundant evidence that timely recognition and treatment of sepsis improves outcomes [17-19]. However, there are many barriers that limit adherence to the Surviving Sepsis Guidelines (SSG) [20, 21]. There is some promising initial work showing that computerized physician order entry can improve compliance with Pediatric Advanced Life Support guidelines [22] and that an EHR can help identify adult patients with sepsis in order to treat them earlier and thus improve morbidity and mortality [20, 21]. However, given the aforementioned drawbacks to implementation of an EHR, there are limitations to what an EHR can do. Given the high prevalence and potential morbidity and mortality associated with sepsis and the fact some mandates to develop systems to facilitate early recognition and treatment of sepsis are in place and more are anticipated [23], a better understanding of how to use EHRs and CDS in this context is imperative.

With this need in mind, we designed a study to test the hypothesis that implementation of CDS within an EHR will improve compliance in treating children with severe sepsis or septic shock. In order to differentiate between the effects of general education about the recognition and treatment of sepsis versus the use of CDS within an EHR, the interventions were implemented in a step-wise fashion including guideline development, site-specific adaptation and implementation and integration into CDS[24]. Our aim of this portion of the study was to evaluate the factors that influence provider compliance with SSG, use a modified Delphi technique to develop a Sepsis Assessment Tool (SAT) and Sepsis Clinical Practice Guideline (sepsis CPG), educate providers, and initiate use of the SAT and Sepsis CPG *prior to* implementation of and incorporation into the EHR.

Materials and Methods:

Design: The study utilized qualitative methods and a modified Delphi technique and is part of a larger study examining the effect of CDS within an EHR on compliance in treating children with severe sepsis or septic shock.

Participants and Setting: The study took place at a tertiary care free standing children's hospital over a five year period of time. A convenience sample of physicians and nurses most likely to care for patients with sepsis participated in interviews and focus groups. This study underwent initial review by the IRB committee and was deemed exempt from ongoing review

Data collection and analysis:

Interviews/Focus Groups – Round 1: In 2011, three investigators facilitated semi-structured interviews and focus groups with physicians and nurses in order to assess preexisting knowledge of the SSG and determine anticipated and experienced barriers to implementing the SSG. These sessions were audio-recorded, transcribed, and de-identified. Two investigators independently coded and analyzed the

physician transcripts for themes and then reconciled themes by consensus discussion. This process was repeated for the nursing transcripts.

Development of SAT and Sepsis CPG: A modified Delphi technique [1] was used to develop the SAT and Sepsis CPG. Utilizing the themes from the interviews and focus groups, two investigators proposed a SAT and Sepsis CPG. Physicians from the focus groups reviewed and gave feedback on the SAT and Sepsis CPG individually via email communication. Their feedback was incorporated into the documents and the documents redistributed to the individual physicians for review. This process was repeated until all participating physicians agreed with the SAT and Sepsis CPG. A similar process was then repeated with selected nursing staff. The final version of the Sepsis CPG was approved by the Infectious Disease Department and the Code Blue and Patient Safety committees

Hospital wide education and implementation of SAT and Sepsis CPG: The SAT, the full page Sepsis CPG and badge-sized laminated cards with a summary of the Sepsis CPG were distributed to all hospital physicians including residents as well as nursing staff. Copies of the SAT and the Sepsis CPG were placed in all patient charts and on code carts.

Investigators provided physician education via Grand Rounds presentations, resident conference presentations, and presentations to physicians from departments most likely to care for patients with sepsis (Pediatric Intensive Care Unit, Emergency Department, Ward, and Hematology/Oncology). These sessions included power point presentations highlighting the importance of the early recognition and treatment of sepsis and the details of the SAT and sepsis CPG, provided opportunities for distribution of materials, added a section on sepsis treatment to PALS classes, and in some cases, highlighted World Sepsis Day and skill practice (Intraosseus line insertion).

Sepsis was designated the hospital's low-volume, high-risk education project for nursing for 2012. Nursing educators led unit-based education sessions for all inpatient and emergency care departments of the hospital as well as hospital-wide Nursing Skills Days.

Interviews/Focus Groups – Round 2: In 2013, three investigators facilitated another round of semi-structured interviews and focus groups with physicians and nurses in order to assess the effects of the educational efforts and their early experiences using the SAT and Sepsis CPG. These sessions were audio-recorded, transcribed, and de-identified. Two investigators independently coded and analyzed the physician transcripts for themes and then reconciled themes by consensus discussion. This process was repeated for the nursing transcripts.

Results:

7 physicians and 8 nurses participated in the first round of interviews and focus groups. 7 physician and 10 nurses participated in the second round of interviews. The major themes with representative quotes are listed in Tables 2 and 3.

At the time of the first interviews and focus groups, there was significant agreement among the physicians and nurses on a number of issues. Both groups felt it is challenging to identify severe sepsis

and shock and they identified a number of barriers to timely treatment including lack of personnel, lack of resources, inability to obtain intravenous (IV) access, hesitation to provide rapid boluses of intravenous fluids, and a hesitation to start vasoactive infusions through peripheral access. Both groups also saw the potential utility of a sepsis assessment tool and hospital-specific clinical practice guidelines.

The SAT and Sepsis CPG are shown Figures 1, Table 1. During the development of the Sepsis CPG, a need for a separate antibiotic table was identified. Recommendations for antibiotic choices for different categories of patients were developed with the guidance of the Infectious Disease Department (See Table 5).

With the second set of interviews and focus groups, which took place after the development and implementation of the SAT and Sepsis CPG and the initial educational efforts, both the physicians and nurses felt the new tools were being used throughout the hospital and that there was more timely awareness and treatment of early sepsis and shock. Physicians specifically reported more comfort with rapid administration of fluids and with placement of intraosseus (IO) lines when peripheral access was not attainable and earlier orders for antibiotics and vasoactive medications.

Both groups, however, identified ongoing concerns and areas for improvement. Physicians expressed significant concern that the tools were too sensitive resulting in false positive identifications. While the nurses felt the tools facilitated communication and could improve nursing confidence, they felt that additional barriers inherent in the culture of their hospital, namely the hierarchy of medicine and a stigma for nurses calling for extra help with a hospital-wide “med stat” activation, would lead to ongoing delays. Both groups, especially the nurses, felt a need for ongoing education including simulation-based training.

Discussion:

This study is part of a larger study investigating the impact of CDS within an EHR on the timely recognition and treatment of severe sepsis and septic shock. Answering this question requires differentiating between the effects of education and implementation of a SAT and sepsis CPG alone and the effects of placing these resources within CDS in an EHR. The purpose of this study was to identify the barriers to adherence with the SSG within our hospital and to develop a SAT and CPG that addressed amenable barriers. Via interviews and focus groups of physicians and nurses, we identified a number of barriers to compliance with the Surviving Sepsis Guidelines including a lack of knowledge of the guidelines, difficulty identifying patients with severe sepsis or septic shock, delays in treatment related to a lack of personnel and resources, and a lack of comfort with some specific interventions such as IO placement and early initiation of vasoactive medications. Via a modified Delphi technique [1], we developed a hospital-specific SAT and sepsis CPG. Repeat interviews and focus groups showed that we had addressed some barriers such as familiarity with the SSG guidelines and comfort with interventions, but needed, among other things, additional education to make further progress.

There is widespread acknowledgement that CPGs are difficult to implement in clinical practice. Cabana et al categorized these barriers as being related to knowledge *(lack of familiarity, lack of awareness)*, attitudes *(lack of agreement with guidelines, lack of outcome expectancy, lack of self-efficacy, lack of*

motivation) and behavior *(patient factors, guideline factors, and environmental factors)[13].* The physicians and nurses who participated in our interviews and focus groups identified barriers related to all 3 of these categories. We addressed the barriers of knowledge via education aimed at improving providers' awareness of and familiarity with the SSG. Our educational efforts, especially skills days, also improved the providers' self-efficacy in specific interventions such as pushing intravenous fluids and initiating vasoactive medications outside of the ICU, attitudinal barriers. By intimately involving end-users in our development of the SAT and sepsis CPG, we attempted to further improve attitudes, specifically providers' agreement with the guidelines and motivation for the efforts to succeed. We addressed the behavioral barrier of guideline factors by developing a SAT and CPG specific to our institution and we addressed the behavioral barrier of environmental factors by incorporating into the CPG a system of mobilizing personnel and resources, the "med stat" activation.

The biggest new issue from the perspective of the physicians was the high sensitivity of the guidelines. As with any high stakes test, there will inevitably be some risk of false positive identifications since lowering the sensitivity could result in an unacceptable risk of missing true cases and attempts to increase the positive predictive value of the SAT have been unsuccessful to date. This concern of physicians will be particularly relevant once the CPS is incorporated into a CDS tool within the EHR. Alert fatigue, "the mental state resulting from receiving too many alerts that consume time and mental energy, which can cause important alerts to be ignored along with clinically unimportant ones p.489 [25]" could compromise the beneficial effects of these efforts.

The biggest new issue from the perspective of the nurses was a hesitancy to activate the CPG, specifically a hesitancy to call for the needed personnel and resources via a med stat activation even though that action was outlined by the CPG. The nurses expressed a sense of obligation to respect the hierarchy of their institution (i.e. not go over the resident's or attending's head and make the decision to activate) and a fear of seeming to overreact or be wrong if the patient ended up not meeting the criteria. As others have recognized, changes in clinical practice do not occur simply on an individual or team level but rather within the context of an organizational or professional culture. Changes on these broader levels can be slow to happen[26].

Of the barriers identified by the physicians and nurses, both those mentioned initially and the remaining barriers discussed form the second set of interviews and focus groups, only a few will be further addressed by incorporation of the SAT and CPG into CDS within an EHR (and the issue of alert fatigue would be exacerbated). Clinical decision support can help with diagnostic decision making [24] by identifying patients who meet certain criteria, helping to overcome the initial barrier of knowledge of the need to activate the guidelines. While there is literature to support the idea that EHRs are more useful for management decisions than for diagnosis [26], our intent is to utilize the discrete data points available within an EHR to supplement clinician assessment of patients who are, or who might be, septic. Clinical decision support also has the potential to make the CPG more accessible and more efficient [24] helping to overcome behavioral barriers related to the guidelines themselves and the time needed to implement them.

Incorporation of the sepsis CPG into CDS at our institution should adhere to the AHRQ-funded CDS Consortium's recommendations [27] in order to maximize its effectiveness and avoid the pitfalls of many CDS tools that are rudimentary, interruptive, unhelpful and unsatisfying to providers [24] We will also need to focus our efforts on the barriers best addressed with such a system – recognition of septic patients and early access to the CPG and order entry for the associated interventions. Given the unlikelihood that CDS will address all the ongoing barriers, as recognized by both the physician and especially the nurse, ongoing education is a must for the success of this initiative and educational materials and didactic sessions must be supplemented with hands-on training and performance feedback [26].

The major limitation of this study is the small sample size of the interviews and focus groups. Obtaining the opinions of additional providers or triangulating the results with other sources of data would have made our results more robust, however, as explored above, the themes started by our nurses and physicians are supported by other studies.

Conclusion:

Clinical decision support within electronic health records has the potential to improve traditionally low compliance with clinical practice guidelines. In this study, we explored the barriers, as perceived and experienced by physicians and nurses, to compliance with the surviving sepsis guidelines in anticipation of incorporating a sepsis CPG into CDS within an EHR. While many of the discovered barriers were addressed during the development of the paper-based SAT and CPG, only the barriers of recognizing septic patients and access to the CPG and associated order entry will be addressed by the addition of CDS. Other barriers will need to be addressed via other mechanisms such as ongoing education incorporating hands-on training and performance feedback.

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Figure 1: Sepsis Assessment Tool (SAT)

RAPID SEPSIS ASSESSMENT *

1

- Two of the following (**one** must be TEMP or WBC):
- Temp >38.5 or < 36
- WBC per table below
- RR - per table below
- HR - per table below
- **IF YES = SIRS (Systemic Inflammatory Response Syndrome)**

2

- Infection suspected?
- **IF YES = SEPSIS**

3

- End Organ Dysfunction? (see criteria below)**
- **IF YES = SEVERE SEPSIS**
- CALL MD (attending physician OR PICU attending or fellow) immediately!
- Consider sending labs and starting ***SEVERE SEPSIS GUIDELINE***

4

- Hypotension?
- **IF YES = SEPTIC SHOCK**
- ***START SEVERE SEPSIS GUIDELINE IMMEDIATELY!***

AGE GROUP	TACHY-CARDIA	BRADY-CARDIA	RESPIRATORY RATE	WBC	SYSTOLIC BP
0 d to 1 wk	> 180	< 100	> 50	> 34	< 65
1 wk - 1mo	> 180	< 100	> 40	> 19.5 or < 5	< 75
1 mo – 24 mo	> 180	< 90	> 34	> 17.5 or < 5	< 100
2 – 5 yrs	> 140	NA	> 22	> 15.5 or < 6	< 94
6 – 12 yrs	> 130	NA	> 18	> 13.5 or < 4.5	< 105
13 - < 18 y	> 110	NA	> 14	> 11 or < 4.5	< 117

** End Organ Dysfunction:
Lethargy/irritability/altered mental status (not just "cranky") OR
Poor perfusion (CRT > 3 secs) OR
Decreased urine output (< 0.5 ml/kg/hr) OR
ANY bilateral infiltrates on CXR + need for oxygen

* Based on

Table 1: Sepsis Clinical Practice Guidelines for Children's Hospital and Research Center Oakland (based on Surviving Sepsis Campaign Guidelines: Critical Care Med 2013; 41: 580-637; www.survivingsepsis.org

Time point	Actions to be initiated, or at least considered, by the end of the time frame.
Time Zero: First point at which anyone considers that a child might be septic	1. **Concern for shock**-Besides fever, tachycardia, and hypotension, some patients present initially only with altered mental status and decreased perfusion (delayed or flash capillary refill) – **REFER TO RAPID SEPSIS ASSESSMENT TOOL!** 2. Call **Medstat** 3. Place **oxygen** on all patients! 4. Initiate attempts at **IV access** and **lab testing (OK to use Broviac/central line)**: (**POC** tests-blood gas, glucose, lytes, lactate. Also CBC, chem 8, blood cultures) 5. Know where **IO** equipment is!
0-15 Minutes – START!	1. If no IV access by 5 minutes, **consider IO!** 2. **PUSH** fluids (isotonic crystalloid) *by hand* over 5 minutes if possible, not on a pump, 20 ml/kg IV, repeat until perfusion improves unless rales or hepatomegaly develop, maximum 60 ml/kg IV . 3. **(Fluid resuscitation will take longer than 15 minutes, but initiate here!)** **4.** Assess **point of care** results and **treat hypoglycemia and hypocalcemia** 5. Order **antibiotics** and give ASAP (Goal for first dose to be in by 30 minutes!) 6. Order **inotropes** to bedside, use if BP low *and* 2^{nd} IV available, MAY give inotropes through PIV or IO, even on the ward!(Dopamine 5-10 mcg/kg/min or epinephrine 0.05-0.3 mcg/kg/min)
15-60 Minutes – REASSESS!	1. Consider **hydrocortisone** for adrenal insufficiency! (25 mg IV under 6 months, 50 mg IV up to 9 years, 100 mg IV if 10 years or older) 2. Reconsider need for **inotropes** if not already being given. 3. Reassess: a. Appropriate **cultures** have been drawn, b. **Antibiotics** given Community Acquired: Ceftriaxone (50 mg/kg, max 2gm) and Vancomycin (15 mg/kg, max 1gm,) Sepsis Acquired in PICU: Meropenem (40 mg/kg, max 2gm) and Vancomycin Sepsis on Oncology/BMT: Meropenem, Vancomycin, Tobramycin (2.5 mg/kg, max 125 mg) c. Sufficient **fluid resuscitation** given
1-4 Hours **(Even if not yet in PICU)**	If blood pressure is *not* normalized, tachycardia is *not* resolved, or still needs inotropes; 1. Consider need for more **fluid boluses** (up to 200 ml/kg). 2. Consider adjusting **inotropes** upwards or adding vasopressors (norepinephrine or vasopressin). 3. May need **blood transfusion.** (Surviving Sepsis Guidelines suggest goal Hgb 10) 4. Consider **pericardial effusion**, **pneumothorax**, and **increased intra-abdominal pressure**. Treat if found. 5. May require **central line** for access and/or monitoring. 6. Consider repeat POC blood gas with lytes and glucose.

Table 2. Themes from Physician Interviews and Focus Groups with Representative Quotes

Round 1: Pre-Education and Implementation	**Round 2: Post-Education and Implementation**
Pediatricians of various specialties are generally unfamiliar with the surviving sepsis guidelines, however, when presented with them, there is a general agreement with the guidelines. ***"I mean we're aware that something exists. Have we ever looked it up? No."***	Pediatricians of various specialties are generally familiar with the SAT and CPG. It is being used in most places in the hospital. ***"Yes. Everyone's seen it."*** ***"I think this is really working."***
There is frequently a delay in the recognition of shock, especially when it is compensated (characterized by a normal blood pressure) ***"The biggest problem—It's clearly recognition."*** ***"We need to work on identification of patients earlier."***	More timely awareness and aggressive care is provided for patients with early sepsis and shock due to the CPG. There is: More comfort with using IOs, more comfort pushing bolus intravenous fluids, and earlier orders for vasoactives. ***"When I say get the IO needle, there's no longer everybody freaks out."*** ***"I don't think you should withhold inotropes while you get a central line."***
The treatment of patients diagnosed with shock does not occur in a timely fashion; institution of a "shock stat" or development of a "shock team" should improve timeliness of interventions ***"In an ideal world, a team would get triggered. They'd put the lines in and resuscitate them."***	There is significant concern that the tools are too sensitive and there are frequent false positives. Physicians need to remember to maintain clinical judgment ***"Too sensitive. Not specific enough."*** ***"SIRS—anybody who's tachycardic and has a fever."***
A barrier to prompt treatment of shock is the inability to obtain adequate peripheral intravenous access and a delay in placement of an intraosseus line ***"One limitation is that the IV is too small, so we can't push fluid."*** ***"I don't think anyone on the floor knows where the IO line is."***	While most providers do not use the tools on these patients, this situation results in the providers beginning to ignore the tools OR a situation in which they feel obligated to use the tools even when they do not apply. ***"I don't feel the positive predictive value is really at all like what we want. I've given antibiotics…where I think I previously wouldn't have in an initial outset. I feel like it puts me in a tight spot medical-legally."***
Many practitioners are hesitant to bolus intravenous fluids too aggressively due to a concern for causing pulmonary edema and/or losing IV access ***"It's mentioned in PALS as a rare possibility*** **(cardiogenic edema).** ***It's part of the culture? Definitely." "They're always worried about their little tiny IV—a 24 gauge in the foot."***	There is still room for additional education using multiple modalities including simulated activations with a specific need to focus on hematology oncology department, residents and the antibiotic table ***"I think the education is the only piece that we could do better on it with the residents."***
Some practitioners are hesitant to start vasoactive medications through a peripheral IV and/or on the pediatric wards ***"I usually think central line before inotropes." "There was a misconception that you couldn't." "As soon as they pull the trigger with inotropes…I have to go defend that."***	

Table 3. Themes from Nurse Interviews and Focus Groups with Representative Quotes

Round 1: Pre-Education	Round 2: Post-Education
Nurses feel there is a need for a CPG and that it will be helpful when treating patients with sepsis ***" Even though there are guidelines, it's not universally known."***	There is overall improvement in recognition and treatment of sepsis I do think the foundation information is effective. ***"The staff know what to identify and when to act and when to call for help and kind of what action to take."*** ***"We do receive people from the ED and actually it seems that they've used some sort of protocol, because they seem to do so much of the work already when the kid comes up to the PICU."***
It is challenging to identify a patient in shock ***"We all recognize a really sick kid, but they're trying to get us to recognize it before it looks that sick…it's already too late to do some of these preemptive things."***	There are still some delays due to: Difficulty accessing the SAT and CPG, Lack of personnel and resources (esp in Day Hospital),Hesitancy to call a med stat (a page-initiated response that brings the Code Blue team to the bedside to assist with a patient who requires additional resources besides those immediately available on the floor), Lack of equipment (esp in Day Hospital), Hesitancy to place an IO (esp in HO population),Hesitancy to push IV quickly or lack of understanding of how to push fluids quickly ***"You don't call a code unless they're not breathing or not have a heart rate. Like a septic code, it never happens."*** ***"Hand-pushing fluids? Yeah, I've never done that and I don't think any of the floor nurses would be comfortable with doing that."***
There is frequently a delay in response from other providers (MD, RT) and a lack of the necessary medications (antibiotics) and equipment on the wards; institution of a "shock stat" or development of a "shock team" should improve timeliness of interventions. ***"Other hospitals…you call a code but it's a shock team…you get 15 people in your room in five minutes."***	
A barrier to prompt treatment of shock is the inability to obtain adequate peripheral IV access and a delay in placement of an IO line ***"The patient was poked, poked, poked, poked…they do hesitate to do the IO."***	
Many practitioners are hesitant to bolus intravenous fluids too aggressively due to general inexperience with pushing fluids by hand, a concern for causing pulmonary edema and/or losing IV access ***"You have to make sure you don't overhydrate after you give this 20*** **(ml/kg)** ***because you can get rales or hepatomegaly."***	
Some practitioners are hesitant to start vasoactive medications through a peripheral IV and/or on the pediatric wards ***"There's no way that even a resident on the floor would know how to order dopamine."*** ***"They wouldn't have a pump. They wouldn't have any of this stuff."***	
Nurses need the authority to initiate the CPG and need to be comfortable initiating treatment. ***"I think people are just afraid to…we don't always open the cart."***	There is a need for culture change because the hierarchy of medicine can lead to a delay in care and there is a stigma associated w med stat activation ***"Because the feeling I think for a lot of the floor is that they have to have the resident assess them first, and then the resident has to call the PICU to say like, 'This kid doesn't sound good. Blah, blah, blah.' And then you have to go through all the steps. It's a half an hour period of time that has to be done through before they'll talk about transferring the kid to the PICU."*** ***"When you declare them septic…there's this enormous pressure that happens."*** ***"And I think there's still a lot of intimidation or fear of independently calling a code of saying, 'This kid's not doing – they meet these guidelines. Call a code.'"*** ***"You don't wanna look ridiculous or like a fool, like you called a code and it wasn't a serious issue."***
	There is a need for more education and training so that everyone, especially first responders, is familiar w assessment tool and CPG. These efforts should focus on introducing the topic to people (given the large number of participants not familiar w the tools) and reinforcing previous instruction (given overall saturation with education on other topics). The educators should use varied strategies such as live instruction, case studies, mock codes. They should distribute cards for badges, more posters ***"I think it just needs to be something that get on – stays on our radars that – then, it gets revisited. It can't just be one big push, and then we forget about it, and move on to the next big thing. So I think that that's the key is just revisiting it all the time until it becomes part of people's vernacular. "I also think that doing some mock assessments or mock codes on a floor is a good idea."***

Table 4: Antibiotic table with recommendations for drug choice based on patient condition

Patient condition	Antibiotic (Give in order listed)
Community-acquired sepsis	Ceftriaxone 50 mg/kg IV (max: 2 grams) Vancomycin 15 mg/kg IV (max: 1 gram)
Sepsis acquired in Pediatric Intensive Care Unit	Meropenem 40 mg/kg IV (max: 2 grams) Vancomycin 15 mg/kg IV (max: 1 gram)
Sepsis in Oncology/Bone Marrow Transplant	Meropenem 40 mg/kg IV (max: 2 grams) Vancomycin 15 mg/kg IV (max: 1 gram) Tobramycin 2.5 mg/kg IV (max: 125 mg)

Appendix 7:

Integration of a Novel Surviving Sepsis Educational Module into PALS Certification Program

Mansour K[1], Shaahinfar A[1], Taukave K[1], Shiring K[1], Flori H[2], [1] UCSF Benioff Children's Hospital Oakland, California, [2] C.S. Mott Children's Hospital, Michigan

Background: Early recognition of sepsis and implementation of therapy improves morbidity and mortality among pediatric patients. Automated triage tools, clinical practice guidelines (CPGs) and other quality efforts improve adherence to consensus treatment guidelines of severe sepsis and septic shock (SS).

Objective:

1.) Contribute to a study examining the impact of an electronic medical record (EMR) with embedded and interactive clinical decision support (CDS) on compliance with American College of Critical Care Medicine (ACCM) and Surviving Sepsis Campaign guidelines (SSCG) and clinical outcomes for neonates and children with SS.

2.) Help address awareness- and knowledge-related barriers in this broader QI effort by incorporating a distinct educational module into the existing Pediatric Advanced Life Support (PALS) courses for residents, nursing staff, and faculty.

3.) Test the hypothesis that a brief introduction to the Surviving Sepsis Campaign principles, as well as our EMR-integrated SS Assessment Tool and CPG would prove to be an effective adjunct to the PALS curriculum.

Methods: A novel educational module was added as a brief narrative segment for all participants of the PALS courses conducted at UCSF Benioff Children's Hospital Oakland (UBCHO) between August 2013 and September 2015. While reinforcing the principles taught in PALS, the module introduced learners to the SSCG, emphasizing the narrower timeframe for optimal fluid administration. Participants also received instruction on the use of the UBCHO SS Assessment Tool and CPG. A total of 126 learners participated during 5 PALS courses. Students completed a voluntary, 5-question written survey to evaluate their impression of the utility of the educational module, the Assessment Tool and the CPG.

Results: 126 surveys were completed and analyzed. 71% of respondents strongly agreed and 24% agreed that the review of SSCG and introduction to the UBCHO Sepsis Assessment Tool and CPG were helpful adjuncts to the Distributive Shock Core (μ=4.6 on a 5-point Likert scale). The vast majority of participants either agreed or strongly agreed that the Assessment Tool (93.7%, μ=4.7) and CPG (92.9%, μ=4.7) would improve the care they provided for septic patients. 96.8% of respondents agreed or strongly agreed that it was appropriate to include the Assessment Tool and CPG in the PALS course (μ=4.7). 112 (88.9%) of the participants felt that "the right amount of time" was spent on the module, while the remaining 14 (11.1%) felt that there was "too little time."

Conclusions: We have developed an EMR-integrated tool and management guideline, which is compatible as a brief adjunct to the comprehensive PALS curriculum, expanding upon the fundamentals and adding to students' knowledge of identification and management of pediatric patients with SS. Learners have overwhelmingly found the educational module to be appropriate and helpful. As we further analyze our participants' post-education adherence to the guidelines, if proven effective, inclusion of our educational module into the PALS core curriculum may be beneficial for all who become certified.

Appendix 8:

Is initial lactate a reliable predictor of outcome in pediatric severe sepsis and septic shock?

Noelle Gorgis MD[1], Shan Ward MD[2], Jeanette Asselin RRT[1], Cynthia Fontana RRT[1], Heidi Flori MD[3]
[1] UCSF Benioff Children's Hospital Oakland, [2] UCSF Benioff Children's Hospital San Francisco, [3] C.S. Mott Chidren's Hospital, Michigan

Introduction:
Hyperlactatemia, a marker for tissue hypoxia and anaerobic metabolism oft elevated in shock, is complex and not well understood. In critically ill adults, high lactate is prognostic for increased morbidity and mortality. Few studies have assessed the association between mortality and initial lactate in septic children.

Methods:
We prospectively identified 169 Pediatric Intensive Care Unit (PICU) patients with severe sepsis/ shock as part of a larger sepsis management study. Initial lactate, drawn within 3 hours of meeting severe sepsis criteria, was evaluated for association with in-hospital mortality by Wilcoxon Rank Sum test and logistic regression adjusting for age and PRISM-III (severity of illness) or PELOD (degree of multi-organ dysfunction) scores. We also evaluated the correlation between initial lactate and PICU and hospital lengths of stay.

Results:
Sixty-five patients had a lactate level within 3 hours of meeting criteria. There was no difference in any variable tested between those with or without initial lactates. Levels were no different if arterial, venous, or capillary ($p=0.1$). Median age was 7.5 years (IQR 1.5 to 15). Three had septic shock and 10 (15%) died. The median initial lactate was 2.9 (IQR 1.95, 10) in non-survivors compared to 2.1 (IQR 1.3, 3.5) in survivors ($p=0.2$). Initial lactate correlated well with PRISM-III (r 0.37, $p< 0.01$) and PELOD (r 0.25, $p=0.05$). Multivariate analysis confirmed no association with mortality but initial lactate was significantly associated with both PRISM-III (OR 1.12, 95% CI 1.0-1.25, $p=0.05$) and PELOD (OR 1.13, 95% CI 1.01-1.29, $p=0.03$). No correlation was found between initial lactate and PICU LOS (r -0.03, $p=0.8$) or hospital LOS (r -0.06, $p=0.06$).

Conclusion:
Our study, unlike adult data, did not show an elevated lactate level to be associated with increased mortality in pediatric severe sepsis patients. Given the strong correlation between initial lactate and both PRISM-III and PELOD scores, this value may instead serve as a valuable early marker of disease severity and multiple end organ dysfunction.

W81XWH 1010682
Gant Chart for 2015 Final Report

Task/Aim	2011 Q4	2012 = Q1	2013 Q2	2014 Q3	2015 Q4	Status
1						**Near Completion***
2						**Near Completion***
3						**Completed**

* See 2015 Spend Plan Justification